

Response to the Department of Health's Consultation on the Standardised Packaging of Tobacco Products

3 July 2012

Japan Tobacco International (*JTI*) is part of the Japan Tobacco Group of Companies, a leading international tobacco product manufacturer.

EXECUTIVE SUMMARY

JTI is categorically opposed to the plain packaging of tobacco products. There is no evidence that plain packaging will work, the consultation process of the Department of Health (DH) considering the measure is flawed, and plain packaging will have serious unintended consequences. Only Option 1 – no change – is appropriate.

JTI's views are based on our experience of how competition between branded consumer goods works, our careful review of the documents forming part of the current consultation, as well as the independent opinions of leading experts, whose reports are being submitted with this response.

Plain packaging – or standardised packaging, i.e., packs with all or nearly all branding removed – is based on a mischaracterisation of the role of packaging. The DH assumes that packaging influences smoking behaviour, particularly of minors. This, however, is not based on, or consistent with, a credible and scientifically rigorous understanding of smoking behaviour, as explained in this response and accompanying expert reports. The DH also ignores what the Government has previously said about why people smoke.

Because it misunderstands the role of packaging, and wrongly assumes that plain packaging will change smoking behaviour, it is not surprising that the DH cannot provide reliable evidence that plain packaging will change smoking behaviour.

There is no evidence that plain packaging will work:

- Three years ago, the DH said there was no evidence that plain packaging would reduce the number of minors smoking. It needs to show that evidence now exists, that plain packaging will have an effect over and above existing tobacco control measures, if plain packaging is to proceed. It cannot do so and the proposal should be dropped.
- The objectives of the DH seek to change smoking behaviour but it has no such evidence to rely on. The 'evidence' it does refer to including a review which is called systematic but is anything but that is unreliable and unconvincing. The individual consumer surveys underlying the 'systematic' review test what people say they will do rather than what they actually do and are unreliable. Grouping them together does not make them reliable.
- Lacking evidence of what the impact would be on smoking behaviour, the DH tries to justify plain packaging using the "best guess" and "subjective views" of its preferred panel of individuals to speculate on the impact of plain packaging. This is not a reliable replacement for evidence of what the impact of plain packaging on smoking behaviour would be. The yet-to-be established 'expert panel' side-steps Better Regulation requirements. Panel membership appears to have been designed to reach a pre-determined result. This process, which the DH failed to complete before consulting, in any event lacks accountability and transparency.
- The materials relied on are so weak that the DH's IA can only say that there are "plausible scenarios" under which plain packaging "could be effective". This falls

well short of what the DH is required to show – there is no "robust and compelling" case that plain packaging will work.

The DH's process does not meet the Government's required standards:

- The consultation and IA are part of a fundamentally flawed policy-making process. The process shows that the DH is ignoring the Government's own Better Regulation principles and is seeking to advance policy despite them.
- Internal DH documents show it has actively sought evidence to support its preferred policy. This reinforces JTI's concern that the DH may well have already decided to introduce plain packaging, despite the lack of evidence. The DH is chasing evidence to justify its preferred policy, instead of examining the evidence to inform its choice of policy.
- Still unable to provide evidence of an impact on smoking behaviour, it appears
 that the DH has introduced additional objectives to reflect the 'evidence' it does
 have. Such attempts to justify its desired policy are against Better Regulation
 principles, and do not resolve the fundamental lack of evidence to justify plain
 packaging.
- The DH is also not giving existing regulatory measures a chance to work, despite its commitment that plain packaging would have to show effects on its policy objectives over and above those of existing measures. Its own display ban measure has not been fully implemented yet. Incessant layering of regulation ignores HM Government's regulatory reform agenda.

Plain packaging is so excessive that its negative effects will be widespread and profound for different aspects of UK society:

• The Exchequer and wider UK economy:

- Already an extremely serious problem, the illicit trade in tobacco products costs the UK Government up to £3.1 billion a year in lost revenue. Plain packaging will worsen this, creating new opportunities for illicit traders to provide counterfeit products (plain or branded) and other illicit tobacco products. Plain packs will be cheaper and easier to fake than branded ones, and plain packaging will make it more difficult to identify counterfeit product. Fuelling the illicit trade normalises criminality and shifts jobs from legitimate UK manufacturers and businesses to organised crime groups, costing the taxpayer and public sector in lost revenue.
- Plain packaging will have a direct impact on investment, trade and jobs. JTI and other manufacturers support 5,700 jobs directly and 66,000 indirectly in the UK, and tobacco generates £12.1 billion in revenue each year for the Government. JTI's commitment to the UK economy is reflected by the fact that, since its £9.4 billion acquisition of the Gallaher Group in 2007 (at the time the largest overseas acquisition ever made by a Japanese company), it has made significant further investments in the UK. Between 2007 and 2014, JTI will have invested over £180 million in its Lisnafillan

manufacturing site in Northern Ireland. Further, in 2012 alone, JTI plans to allocate approximately £75 million to (a) development and training of its employees in Northern Ireland; (b) annual salaries into the Northern Irish local economy; (c) spending on UK suppliers of packaging materials; and (d) providing business for over 100 Northern Ireland companies.

- The anticipated shift to the illicit trade and the changes to the competitive structure of the tobacco market resulting from plain packaging risk significant job losses, as well as reductions in income and economic activity in the UK. The UK is meant to be 'open for business' and growth is meant to be the Government's top priority. Plain packaging will seriously undermine that.
- Tobacco product manufacturers, including JTI, and the wider tobacco market: plain packaging will significantly erode JTI's brand equity, severely damage competition in the market, and will eliminate pack innovation. Plain packaging will raise barriers to entry for new brands (other than for 'commodity' products). Expert analysis accompanying this response demonstrates:
 - as brand awareness degrades, competition initially becomes fixated on one or two brands for most price segments (damaging within-price-segment competition) followed by large-scale downtrading into lower-price products;
 - o for even modest degrees of brand degradation, average prices of tobacco products (and cigarettes in particular) fall. The price effects on individual brands vary on account of market structure changes; and
 - o an increase in concentration (even for modest degrees of brand awareness degradation) that should be considered of interest and concern to policymakers.
- Retailers: plain packaging will have significant negative effects on retailers. Transaction times will increase. Margins will be eroded by further downtrading. As tobacco products make up a significant proportion of the turnover of many small retailers, plain packaging may have significant cash-flow and credit implications for them. Such an impact is particularly detrimental in the current economic and bank-lending climate. Further, an increase in the illicit tobacco trade means community-based shops will be further undercut and undermined by criminal gangs.
- **Consumers** will be denied the ability to choose branded products.
- **Minors:** the DH seeks to protect minors and those from the most disadvantaged backgrounds, but plain packaging risks leading them to buy from the cheaper, illegal and unregulated market.

Plain packaging unjustifiably infringes fundamental legal rights to property, expression and trade. It deprives JTI of its most valuable assets – its brands and trade marks. It is wrong for any liberal democracy and free market economy to go this far. The legality of the only such law to be adopted – in Australia – is currently

the subject of not one but three different challenges (before the World Trade Organization and elsewhere).

The consultation does not consider – as it must – whether there are more proportionate alternatives to its fundamentally flawed plain packaging proposal. The consultation and the IA do not try to calculate the benefits of avoiding further regulatory burdens.

Alternative, effective and proportionate solutions to legitimate public health goals are available, including:

- Ensuring better enforcement including more penalties and prosecutions to tackle the illicit trade in tobacco products. Greater enforcement is likely to be fiscally positive over the long term, as increased tax revenues more than compensate for increased enforcement costs.
- Giving greater resources and manpower and priority to effective and targeted enforcement of the current regulatory regime, including negative licensing and updating, as well as enforcing, the under-utilised provision of the 1933 Act on the confiscation of cigarettes from minors.
- Reinforcing retail access prevention measures, such as 'No ID, No Sale'.
- Following the Scottish example and penalising proxy purchasing by adults.
- Following the Scottish example and penalising the purchase or attempted purchase of tobacco products by minors.
- Targeted public information campaigns to quickly and effectively raise the awareness of tobacco control measures, such as negative licensing schemes.

Were plain packaging to be introduced despite all the points above, it would lay down a precedent for plain packaging of a whole range of consumer products – the risk of which is demonstrated by recent consideration (by the UK Parliament's Health Select Committee) of plain packaging for alcohol.

In conclusion, there is no justification for the UK to take plain packaging forward. It would be particularly inappropriate to do so now, when similar measures are also being considered by the EU. UK taxpayers are currently funding not one but two consultations on a measure which will not work, and which will have serious unintended consequences. There was no evidence in 2008, and there is no evidence now: plain packaging will not work, and will have serious unintended consequences. Option 1 is the only appropriate option.

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1. INTRODUCTION

- 1.1 JTI is categorically opposed to the plain packaging of tobacco products (Option 2). Further packaging regulation is not appropriate or necessary. JTI supports Option 1 (which would retain the existing regime without adding more to the already stringent packaging regulation).
- 1.2 Tobacco products carry risks to health. We believe that appropriate and proportionate regulation is both necessary and right. Minors should not smoke and should not be able to obtain tobacco products. Everyone should be appropriately informed about the health risks of smoking. These core principles are central to our Code of Conduct, Global Marketing Standard, operational policies and the way JTI does business.
- 1.3 Tobacco is a legal product, and manufacturers compete among themselves for their share of the legal tobacco market. JTI acts with openness and transparency about the products adult smokers choose to purchase. Adults who choose to smoke are entitled to be treated fairly, and have the right to choose the product they prefer.
- 1.4 The DH's 16 April 2012 consultation on standardised packaging of tobacco products (the *Consultation*) refers to both "*standardised*" and "*plain*" packaging. Whilst the Consultation does not elaborate the precise packaging requirements that the DH may propose and fails to illustrate what its envisaged packs would, in fact, look like, 'plain packaging' is the internationally accepted terminology. JTI refers to 'plain packaging' throughout this response (the *Response*).
- 1.5 JTI is part of the Japan Tobacco Group of Companies, a leading international tobacco product manufacturer. It markets world-renowned brands such as Winston, Mild Seven and Camel. Other international brands include Benson & Hedges, Silk Cut, Sobranie of London, Glamour and LD. With headquarters in Geneva, Switzerland, and net sales of USD 11.2 billion in the fiscal year ended 31 December 2011, JTI has about 25,000 employees and operations in more than 120 countries.
- 1.6 Since April 2007, Gallaher Limited (Gallaher), the UK-based tobacco products manufacturer, has also formed part of the Japan Tobacco Group. Plain packaging will have a direct impact on investment, trade and jobs. JTI and other manufacturers support 5,700 jobs directly and 66,000 indirectly in the UK, and tobacco generates £12.1 billion in revenue each year for the Government. JTI's commitment to the UK economy is reflected by the fact that, since its £9.4 billion acquisition of the Gallaher Group in 2007 (at the time the largest overseas acquisition ever made by a Japanese company), it has made significant further investments in the Between 2007 and 2014, JTI will have invested over £180 million in its Lisnafillan manufacturing site in Northern Ireland. Further, in 2012 alone, JTI plans to allocate approximately £75 million to (a) development and training of its employees in Northern Ireland; (b) annual salaries into the Northern Irish local economy; (c) spending on UK suppliers of packaging materials; and (d) providing business for over 100 Northern Ireland companies. In this response, we use the term 'JTI' to refer collectively to JTI and Gallaher.

- 1.7 JTI has its UK headquarters in Weybridge, Surrey, and has a long-standing, significant presence in the UK market. Its UK cigarette brand portfolio includes Benson & Hedges, Silk Cut, Camel, Mayfair, Sovereign, Sterling and Berkeley, as well as a number of other tobacco products including roll-your-own tobacco (*RYO*), also known as hand-rolled tobacco (such as Amber Leaf), cigars (such as Hamlet) and pipe tobacco (such as Condor). JTI manufactures product for the UK market at sites in the UK (in Northern Ireland) and outside it (for example, in Germany). In the UK alone, JTI employs over 1,800 people. Further, JTI has made significant duty and tax payments to the UK Exchequer. In 2011, JTI made payments of over £3.6 billion in Tobacco Product Duty. In total, JTI paid over £4.6 billion in tax in 2011.
- 1.8 JTI notes at the outset that it does not agree with the assertions made in the Consultation and the materials accompanying it. The fact that JTI does not respond to all of them in this Response, which is targeted at the specific questions being consulted upon, should not be treated as an acceptance of these other assertions.

OUTLINE OF JTI'S SUBMISSION

- 1.9 This Response addresses the following:
- (a) The inconsistency and inadequacy of the Consultation and accompanying Impact Assessment (the *IA*) with the UK's own Better Regulation principles (Section 2).
- (b) JTI's fundamental objections to the flawed plain packaging proposal, in particular:
 - (i) there is no reliable evidence, and certainly no "robust and compelling" case, that plain packaging will achieve public health objectives (Section 3);
 - (ii) plain packaging impedes and restricts lawful activity whilst facilitating illegal activities (Section 4);
 - (iii) plain packaging will have other negative effects on consumers, retailers and connected industries (Section 5); and
 - (iv) plain packaging will deprive JTI of its most valuable assets, infringing fundamental legal rights (Section 6).
- (c) The alternative regulatory solutions that would better achieve the Government's objectives whilst avoiding the serious negative consequences of plain packaging (Section 7).
- 1.10 The main body of the Response is supported by Schedules and Annexes. In particular, Schedules 1 and 2, together with Annexes 1 to 12, set out in detail the evidence on which JTI relies:

For example, some of the points made in paragraphs 2.1 to 2.6 of the Consultation. JTI's outline views on smoking and health issues are set out at http://www.jti.com/how-we-do-business/smoking-and-health/.

- (a) Schedule 1: the importance of a properly conducted IA and the insufficiency of the IA in this Consultation;
- (b) Schedule 2: a critique of the DH-commissioned report which seeks to review evidence on plain packaging entitled, "*Plain Packaging, a Systematic Review*" (the *Systematic Review*) which accompanies the Consultation;
- (c) Schedule 3: JTI's summary response to the questions set out at Appendix A to the Consultation. This form is provided for completeness and convenience only. JTI's full review of the arguments, evidence and alternative solutions is set out in this Response;
- (d) Schedule 4: JTI's response, where appropriate, to the questions outlined in Appendix B to the Consultation; and
- (e) Annexes 1 to 12 contain the expert reports of:
 - (i) **Professor Steinberg**. Laurence Steinberg, Distinguished University Professor and Laura H. Carnell Professor of Psychology at Temple University, Philadelphia, United States of America, is a leading authority on adolescent judgement, decision making and risk-taking. His 2010 report, entitled "Adolescent Decision Making and the Prevention of Underage Smoking" (Professor Steinberg's Report) is at Annex 1, and is available at http://www.jti.com/how-we-do-business/resources/. Professor Steinberg explains that because minors are naturally more prone to risk-taking behaviour than adults, only measures that control minors' ability to obtain tobacco products and remove cigarettes from their social network will be effective in reducing smoking among minors.
 - Professors Dhar and Nowlis. Ravi Dhar is George Rogers Clark Professor of Management and Marketing and Director of the Centre for Customer Insights at the Yale School of Management, New Haven, United States of America. Stephen Nowlis is August A. Busch, Jr. Distinguished Professor of Marketing in the Olin School of Business at Washington University in St. Louis, United States of America. Both are award-winning marketing professors at leading universities in the United States, who have published extensively on the subject of consumer behaviour and decision making. Professors Dhar and Nowlis's 2010 report, entitled "Report on Adult Consumer Behaviour and Decision-Making in the Context of Smoking" (Professors Dhar and Nowlis's Report) is at Annex 2, and is available at http://www.jti.com/how-we-do-business/resources/. Professors Dhar and Nowlis conclude that plain packaging is unlikely to be effective as a means to reduce smoking and encourage quitting by adults.
 - (iii) **Professors Zimmerman and Chaudhry**. Alan Zimmerman is Professor of International Business and leads the International Business Programme at City University of New York, College of Staten Island, New York, United States of America. Peggy Chaudhry

school of Business, Villanova, Pennsylvania, United States of America. They are the co-authors of "The Economics of Counterfeit Trade" and have been involved in an extensive set of research projects examining various aspects of the global trade in illicit products. Their 2012 report entitled "The Impact of Plain Packaging on the Illicit Trade in Tobacco Products" (Professors Zimmerman and Chaudhry's Report) is at Annex 3, and is available at http://www.jti.com/how-we-do-business/resources/. Professors Zimmerman and Chaudhry's expert opinion is that plain packaging for tobacco products will worsen the illicit trade in tobacco products as it would open a number of new opportunities for illicit traders while making it more difficult for consumers, retailers and law enforcement agencies to differentiate between genuine and fake packs.

- (iv) **Dr** Lilico. Andrew Lilico is Director and Principal of Europe Economics, London. He is an expert in microeconomic analysis and regulatory impact assessment. Dr Lilico has prepared two relevant reports. First, his report, "Economic Analysis of a Display Ban and/or Plain Packs Requirement in the UK, A Report from Europe Economics" (Dr Lilico's 2008 Report) is at Annex 4, and is available at http://www.jti.com/how-we-do-business/resources/. Secondly, Dr Lilico has prepared a report entitled "Economic Analysis of a Plain Packs Requirement in the UK, A Report from Europe Economics" (**Dr** Lilico's 2012 Report) which reproduces and expands, with economic modelling, the relevant sections of his 2008 Report. Dr Lilico's 2012 Report is at Annex 5, and is available at http://www.jti.com/how-wedo-business/resources/. Dr Lilico anticipates, amongst other things, that a market reaction to plain packaging would be fixation on one or two brands for most price segments (damaging within-price-segment competition) and large-scale downtrading into lower-quality/price products. Innovation would be all but eliminated, and barriers to entry would be raised. His model demonstrates the significant changes in market structure, price and market concentration as a result of a plain packaging measure.
- (v) **Professor Cave**. Martin Cave is a Visiting Professor at Imperial College Business School and, from January 2012, Deputy Chair of the Competition Commission. His 2010 report, "Better Regulation and Certain Tobacco Control Measures" (Professor Cave's Report) is at Annex 6, and is available at http://www.jti.com/how-we-do-business/resources/. Professor Cave notes that the process of deciding how to regulate tobacco requires a careful and thorough specification of objectives, identification of alternatives and weighing up of evidence. Because plain packaging is untried, the evidence basis for introducing it should be the best available, reliable and needs to include a careful assessment of whether equally effective and more targeted measures should be applied first. In Professor Cave's opinion, there appear to be a number of alternative targeted measures available.

- (vi) **Professor Gervais**. Daniel Gervais is Professor of Law at Vanderbilt University Law School, United States of America. He is a leading expert on international intellectual property law and author of "The TRIPS Agreement: Drafting History and Analysis". His 2010 report entitled "Analysis of the Compatibility of Certain Tobacco Product Packaging Rules with the TRIPS Agreement and the Paris Convention" (**Professor Gervais' Report**) is at Annex 7, and is available at http://www.jti.com/how-we-do-business/resources/. Professor Gervais explains that plain packaging is not compatible with international trade rules and that to the extent that the World Trade Organization (**WTO**) Member cannot satisfy the burden of showing that plain packaging will achieve its legitimate public policy objectives, the measure can be expected to be found incompatible with WTO obligations.
- (vii) **Professor Devinney**. Timothy M. Devinney is Professor of Strategy at the University of Technology, Sydney, Australia; Co-joint Professor in the Faculty of Medicine at the University of New South Wales, Australia and a Visiting Professor at the Institute of Management at Humboldt University, Berlin, Germany. He is an expert in consumer survey research, experimental methods and associated statistical analysis. Professor Devinney has prepared two relevant reports: first, his 2010 report entitled "Analysis of Consumer Research Evidence on the Impact of Plain Packaging for Tobacco Products" (**Professor Devinney's 2010 Report**) is at Annex 8, and is available at http://www.jti.com/how-we-do-business/resources/; secondly, his 2012 report entitled "Analysis of Consumer Research Evidence on the Impact of Plain Packaging for Tobacco Products (Updated to 2012)" (**Professor Devinney's 2012 Report**) is at Annex 9, and is available at http://www.jti.com/how-we-do-business/resources/.
- (viii) **Dr Keegan**. Warren J. Keegan is the Distinguished Professor of Marketing and International Business at the Lubin School of Business, Pace University, New York, United States of America, and a Visiting Professor at ESSEC, Cergy-Pontoise, France. He is Head of Keegan & Company LLC, Rye, New York, United States of America. particular, he is an expert in consumer survey research and analysis. His 2008 report entitled "Analysis of Consumer Survey Evidence Relevant to the UK Department of Health Consultation on the Future of Tobacco Control" is at Annex 10; his 2009 report entitled "Analysis of Consumer Survey Evidence Relevant to the UK Department of Health Consultation on the Future of Tobacco Control: Supplemental Report" is at Annex 11; and Exhibit 7 ("Plain Packaging Study Reviews") of his 2010 report entitled "Analysis of Consumer Survey Evidence Relevant to DG SANCO's Proposal to Increase the Size of Health Warnings on Tobacco Packaging" is at Annex 12 (collectively, Dr Keegan's Reports). Dr Keegan's Reports are available at http://www.iti.com/how-we-do-business/resources/. Between the two of them, Professor Devinney and Dr Keegan have independently as experts reviewed the publicly available consumer survey studies

relevant to plain packagingⁱⁱ and found that they do not constitute reliable evidence that plain packaging will change actual smoking behaviour, either by preventing minors from smoking or by increasing smoking cessation among minors or adults.

Professor Devinney concurs with the relevance of Dr Keegan's evaluation criteria outlined in Dr Keegan's Report. Professor Devinney's 2010 Report and his 2012 report therefore build on Dr Keegan's criteria. See Professor Devinney's 2010 Report, paragraphs 1.3 to 1.5 and 2.1; and Professor Devinney's 2012 Report, paragraphs 2.1 and 2.12.

2. BETTER REGULATION

- 2.1 JTI supports legislative and regulatory measures on tobacco control which meet internationally and nationally accepted principles of Better Regulation. However, JTI will question, and where necessary challenge, regulation that is flawed, unreasonable, disproportionate or without evidential foundation.
- 2.2 The Coalition Government has repeatedly committed itself to Better Regulation. On taking office, the Prime Minister stated that "I want us to be the first government in modern history to leave office having reduced the overall burden of regulation rather than increasing it". The Coalition Government has said that it will "resist the temptation for hasty regulation, even under intense media pressure", 4 and that it will introduce regulation only as a "last resort" and in accordance with its Better Regulation principles. 6 Those principles state that the Government will regulate to achieve its policy objectives only:
- (a) "having demonstrated that satisfactory outcomes cannot be achieved by alternative, self-regulatory, or non-regulatory approaches;"
- (b) "where analysis of the costs and benefits demonstrates that the regulatory approach is **superior by a clear margin** to alternative, self-regulatory or non-regulatory approaches;" and
- (c) "where the regulation and the enforcement framework can be implemented in a fashion which is demonstrably proportionate; accountable; consistent; transparent and targeted". (Emphasis added.)
- 2.3 Better Regulation principles also require a "robust and compelling" case to be made before regulation is taken forward.
- 2.4 Reflecting these core principles, Professor Cave has identified the following 'checklist' of core Better Regulation requirements which would need to be met for regulatory interventions like plain packaging:
- (a) "Clarity of objectives the nature and scale of the problem which the regulation seeks to address must be clearly defined and the objectives of the regulation must be clearly stated and legitimate;
- (b) Targeting and proportionality regulation should be focussed on the particular problem identified and be no more intrusive than is required and proportionate to the goal;
- (c) Evidence-based assessment the evidence base for the policy must be both the best available and reliable; there must be evidence to support the proposal over alternative options; impact assessments must be conducted and must be as accurate and complete as is reasonably practicable;
- (d) Incremental value regulators must review and evaluate existing legislation (including whether it is being effectively enforced) and other options before regulating further; and

- (e) Enforceability regulation must be capable of being complied with and enforced effectively".8
- 2.5 These are the benchmarks, together with the Government's "Operating Principles", 9 against which JTI has examined the Consultation and accompanying IA. JTI has sought to point out in this Response any action taken or contemplated by the DH that falls short of these fundamental requirements.
- 2.6 In summary, the Consultation and IA manifestly fail to satisfy these principles. A detailed critique of the fundamental flaws of the IA is set out at Schedule 1. However, JTI wishes to highlight at this stage seven fundamental flaws in the approach taken by the Consultation and IA.

A. AN INCOMPLETE AND FLAWED EVIDENCE BASE

- 2.7 It is a fundamental principle of Better Regulation that clear, reliable evidence a "robust and compelling" case must be available to support any given proposal. The strength of the evidence base is especially important here as no country has actual experience of plain packaging. Professor Cave states: "better regulation principles require regulatory interventions to be supported by credible and impartial evidence which shows that the measure proposed will be effective in achieving a legitimate, stated goal. Where the proposed measure is novel, in the sense that it is being applied for the first time, and where, in consequence, there is no direct evidence of its effect, there must be impartial and credible indirect evidence". (Emphasis added.)
- 2.8 The IA agrees and states that "[f]or tobacco control policies to be justified the impact on smoking behaviour and the consequent improvement in health need to be sufficiently large to justify the related costs". [1] (Emphasis added.)
- 2.9 In 2009, after an extensive public consultation on the issue (the DH's 2008 Future of Tobacco Control Consultation (the *FTC Document*)), the DH said that there was no evidence that plain packaging reduced smoking uptake amongst minors or helped people to quit. On 25 June 2009, the then Minister of State for Public Health stated:

"No studies have been undertaken to show that plain packaging of tobacco would cut smoking uptake among young people or enable those who want to quit to do so. Given the impact that plain packaging would have on intellectual property rights, we would undoubtedly need strong and convincing evidence of the benefits to health, as well as its workability, before this could be promoted and accepted at an international level—

See, for example, the first of the UK Government's Better Regulation operating principles, which provides that regulation should not be taken forward unless a "robust and compelling" case has been made. See also, in the EU context, the European Commission's Impact Assessment Guidelines, available at http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_en.pdf, which emphasise, at paragraph 4.1, that "Good quality data – facts as well as figures – are an essential part of an IA.... Particular attention needs to be paid to quality and credibility of data".

The UK is effectively a 'first mover' in this case as there is no market in the world that has plain packaged tobacco products. While Australia has passed the Australian Plain Packaging Act 2011, it does not come into effect until the end of 2012.

especially as no country in the world has introduced plain packaging". ¹² (Emphasis added.)

- 2.10 This is after the then Secretary of State for Health told Parliament in 2008 that "there is no evidence base that [plain packaging] actually reduces the number of young children smoking". ¹³ (Emphasis added.)
- 2.11 The DH effectively restated this position regarding the absence of evidence in May 2011.

A flawed 'evidence base'

- 2.12 No reliable evidence let alone "robust and compelling" evidence is available to support taking plain packaging forward.
- 2.13 Materials made available pursuant to Freedom of Information Act (*FoIA*) requests show that the DH recognised from the outset when considering the evidence that would be required to support a plain packaging proposal that it would be difficult to obtain reliable evidence: "On reducing smoking prevalence, we would want the review to point out how plain packaging might work to reduce smoking prevalence (both in uptake and supporting quitting), but we are not sure whether the evidence-base would enable us to say anything more definite". ¹⁴ (Emphasis added.)
- 2.14 The DH has commissioned the Systematic Review to "inform responses to this Consultation and any subsequent policy making". The Systematic Review ignores its own finding that "there are a number of limitations with the plain packaging studies found". This finding is unsurprising given that expert analysis demonstrates that the consumer survey evidence cited in the Consultation as the basis for a plain packaging measure is not reliable (discussed further in Section 3).
- 2.15 Grouping the studies into a review which is systematic in name only does not change the fact that its underlying component parts are flawed. As Schedule 2 to this Response demonstrates, the Systematic Review itself is also methodologically flawed. Reinforcing the concerns the DH had expressed in the FoIA disclosure quoted at paragraph 2.13 above, the DH's problem is that there is no evidence to justify plain packaging.

An incomplete 'evidence base'

- 2.16 The materials relied on by the DH are also even on the DH's own analysis incomplete.
- 2.17 The Consultation and IA recognise that any plain packaging proposal needs to be justified by reference to the impact on actual smoking behaviour. Indeed, the DH's objectives refer to smoking behaviour. ¹⁷ But the DH has no actual behavioural evidence to rely on.

^v In an email dated 10 May 2011, DH has stated that "there isn't any hard evidence to show that [plain packaging] works". This email was part of the material disclosed on 19 August 2011 pursuant to a Freedom of Information Act request by Philip Morris International (Ref TO00000633879).

- 2.18 The IA refers to further evidence that the DH is still seeking regarding the impact of plain packaging "on smoking behaviour and quitting". The proposal is to establish an expert panel to assess quantitative behavioural change. JTI's detailed concerns with this process are set out in Section 3 below, but there are three fundamental points to highlight:
- (a) The use of subjective judgements is no substitute for proper behavioural evidence. As a matter of social science standards, the use of the subjective judgements of individuals as a substitute for actual behavioural evidence to justify new regulatory interventions is flawed. For example, it ignores existing literature which states that "expert judgments should be used with caution, not to replace 'hard' science". ¹⁹
- (b) **Biased and self-interested experts will not be excluded.** The DH is inappropriately seeking to introduce policy based on the "subjective" views and "best guess" as to what smokers may actually do from a panel of individuals who, it appears, have a vested interest in the outcome. Without explaining, in a transparent manner, why it is not inviting independent experts to participate in this panel, the DH is choosing experts for whom impartiality was "impractical". The DH will, in other words, appoint a panel of biased experts, upon whose subjective judgement they will rely in determining whether plain packaging for tobacco products should be implemented. This contravenes HM Government's guidelines on the choice and selection of experts, which requires it to draw upon a "range of appropriate expert sources" that "should be sufficiently wide to reflect the diversity of opinion among experts in the appropriate field(s) in a balanced way". ²⁰
- (c) **Even this 'evidence' is not available yet.** The DH is consulting on measures without having first obtained the inputs it has itself identified as necessary. This is particularly shocking given that it has been clear since December 2008 that it was evidence on smoking **behaviour** that the DH recognised needed to be 'developed' if plain packaging could be taken forward. Vi
- 2.19 The materials put forward by the DH are so weak that the best the IA can say is that there are "plausible scenarios" under which plain packaging "could be effective", and that there is a "possible impact" on consumption. It is a cornerstone of Better Regulation principles that clear evidence is necessary for regulatory intervention (see, for instance, the requirement for "robust and compelling" evidence²²). Failure to obtain such key evidence renders the Consultation both premature and deficient. It also evidences why stakeholders are entitled to be concerned about the apparently biased and pre-determined nature of this Consultation.

Note the comment from Alan Johnson MP, then Secretary of State for Health, 9 December 2008: "As part of their consultation, the Government also sought views on whether to bring forward innovative proposals on tobacco packaging. We believe that more needs to be done to develop our understanding of how the packaging of tobacco products influences smoking by both adults and young people. The Government will therefore keep tobacco packaging under close review" (emphasis added), available at: http://www.publications.parliament.uk/pa/cm200809/cmhansrd/cm081209/wmstext/81209m0001 htm#08120943000015.

B. THE DH HAS SHIFTED THE EVIDENTIAL 'GOAL POSTS' TO TRY TO ACHIEVE THE DESIRED POLICY

- 2.20 The DH's stated public health objectives, set out in the first three bullets of paragraph 3.1 of the Consultation (the *Objectives*), seek to change smoking behaviour, namely by:
- (a) discouraging young people from taking up smoking;
- (b) encouraging people to quit smoking; and
- (c) helping those who have quit, or are trying to quit, to avoid relapse back to smoking. vii
- 2.21 FoIA disclosure shows that the DH actively sought evidence presuming that plain packaging will be effective: "to maximise its usefulness, the review will need to draw out what the additional benefits of plain packs would be" (emphasis added), and "on reducing smoking prevalence, we would want the review to point out how plain packaging might work to reduce smoking prevalence".²³
- 2.22 However, the DH has no actual behavioural evidence to rely on. Thus it has created a series of "mechanisms by which standardised packaging might work", set out at paragraph 3.2 of the Consultation (the **Mechanisms**), ²⁴ and presented evidence on those instead.
- 2.23 The DH compounds this flawed approach with the introduction of a panel of experts who, by DH's own admission will not be impartial, to consider this evidence and provide their subjective judgement as to whether, and if so by how much, plain packaging will contribute to the effect of other regulatory measures.
- 2.24 The DH may be proceeding on the assumption that the Mechanisms will drive behaviour. It has not presented any evidence to support this assumption. Indeed, as JTI demonstrates below, the assumption is wrong as packaging is not a predictor of smoking behaviour (see paragraph 3.5 below).
- 2.25 The DH's approach to the Consultation in this way is contrary to fundamental principles of Better Regulation and good administration which require a consultation to be open, independent, impartial, and not prejudging of the outcome.²⁵ The fact that this is a controversial issue is exactly why procedural safeguards have to be met.

C. INADEQUATE EVALUATION OF EXISTING REGULATION

2.26 Critical in the context of Better Regulation is the need to consider the necessity for new regulation in light of existing regulatory measures. The IA recognises this point, noting that a "policy to introduce standardised tobacco packaging would need to be justified and be based on expected benefits over and above existing tobacco control measures". ²⁶ Professor Cave echoes this view when

vii JTI notes that the fourth bullet point in paragraph 3.1 of the Consultation is derivative of the Objectives (it will only happen if some or all of the Objectives happen, and as a result consumption of tobacco products declines) and so does not consider this separately.

he considers tobacco control measures in his report: "regulators must review and evaluate existing legislation... and other options before regulating further". 27

- 2.27 The Consultation and accompanying IA fail to give adequate consideration to the interrelationship between plain packaging and recent regulatory initiatives. Many of these measures have not even been implemented or at most have only been implemented in the relatively recent past. Of particular concern is the fact that the DH is now considering a far-reaching and untested regulatory restriction without any apparent consideration of the extent to which the Consultation's Objectives are being, or will be, addressed effectively by the following recent initiatives:
- (a) smoking in enclosed public places and workplaces was banned in England from 1 July 2007 (similar measures had already come into force in Scotland on 26 March 2006, Wales on 2 April 2007 and Northern Ireland on 30 April 2007);
- (b) the minimum age of sale for tobacco was raised from 16 to 18 from 1 October 2007 in England, Wales and Scotland, and from 1 September 2008 in Northern Ireland;
- (c) the introduction of graphic health warnings on tobacco products, which was phased in from autumn 2008;
- (d) 'negative licensing', which came into effect from 1 April 2009 in England and Wales, whereby a retailer's right to sell tobacco may be suspended or withdrawn if that retailer is caught selling or supplying tobacco products to minors; viii
- (e) the ban on the sale of tobacco from vending machines across England on 1 October 2011, 1 February 2012 in Wales and 1 March 2012 in Northern Ireland. Similar legislation is to be introduced in Scotland but the date of implementation has not been confirmed;
- (f) measures to penalise 'proxy purchasing' by adults and the purchase or attempted purchase of tobacco products by minors introduced in Scotland in April 2011;²⁸
- (g) the tobacco display ban, which prohibits the permanent display of tobacco products by retailers, came into force for large shops in England on 6 April 2012 and will be implemented in Northern Ireland on 31 October 2012 and in Wales on 3 December 2012. Small shops and other outlets to which the display ban applies (the vast majority of retail outlets selling tobacco products) must comply by 6 April 2015 in England, Northern Ireland and Wales.

The DH stated that the objective of negative licensing measure is: "to prevent children buying tobacco, through strengthening sanctions against retailers who sell tobacco to children under the legal minimum age". See "Consultation on Under-Age Sale of Tobacco" (3 July 2006), DH, page 33, available at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_41367_33.pdf.

- Similar legislation is to be introduced in Scotland but no implementation date has been confirmed; and
- (h) *increases in the duty tax payable on the purchase of tobacco products.* In the most recent example of this, since 21 March 2012, consumers have had to pay 37 pence more for a packet of 20 cigarettes.^{ix}
- 2.28 There has been no holistic review of the effectiveness of the above measures, looking at their impact as a whole, before concluding whether it is necessary to move forward.
- 2.29 Reinforcing these concerns, the introduction of the display ban was said in the impact assessments which accompanied its introduction to contribute to the same objectives (reducing smoking initiation amongst minors and helping adults to quit) identified now. Yet the DH is now consulting on plain packaging even before the effect of the display ban had been tried, let alone its presumed effectiveness tested.
- 2.30 The view of the Regulatory Policy Committee (*RPC*) regarding the IA raises the same concern: "While the IA does acknowledge the "current tobacco control policies", the IA would also benefit from explaining more clearly how this proposal will interact with these other recent proposals in this area, such as the ban on display of tobacco products at point of sale. This will allow the marginal costs and benefits of this proposal to be assessed at final stage".²⁹
- 2.31 HM Government's own statistics indicate that smoking by minors is falling. For example, the 2011 annual government survey of smoking among minors under the age of 16 shows that smoking prevalence has continued to decline.³⁰ Prevalence of 'regular' smoking (defined as usually smoking at least one cigarette per week) fell to 6% in 2007 after having remained constant at 9% for the previous four years. In 2010, there was a further drop to 5%, the lowest rate recorded since the survey began.³¹
- 2.32 The IA's own projection for the impact of the display ban on smoking prevalence reinforces the need to assess carefully the workings of the existing measures before regulating further. The IA anticipates that the display ban will "help to sustain the medium to long term downward trend in smoking prevalence". In particular, the IA believes that the full effect of the display ban will be a fall in smoking prevalence among 11 to 15 year olds from 5% to 4.2%.

See "Budget 2012", HM Treasury (March 2012), page 70. In reference to the increase in tobacco duty, the Chancellor of the Exchequer stated that "There is clear evidence that increasing the cost of tobacco encourages smokers to quit and discourages young people from taking it up" (see http://www.bbc.co.uk/news/business-17464095). Previous increases in the 2011 Budget in duty payable on tobacco and alcohol were justified in the Budget document as "fair excise duties ... which contribute to deficit reduction whilst supporting health objectives" – see "Budget 2011", HM Treasury (March 2011), page 39. Also see "Tobacco Products Duty Rates", HMRC, page 2, available at http://www.hmrc.gov.uk/budget2012/tiin-0730.pdf.

See, for instance, the impact assessment in relation to the introduction of the display ban that accompanied the Health Bill, "Impact Assessment of prohibiting the display of tobacco at point of sale" (13 May 2009), which provides that, "The primary objective is to reduce smoking uptake in under-18s. The policy may also provide a more supportive environment for those trying to quit, and may help prevent the health message from being undermined".

- 2.33 Therefore, the DH must consider what, if anything, plain packaging can do to accelerate the existing and projected downward trend that the DH has itself identified. It has failed to do so. Recent statistics and the projection for continuing success are sufficiently important to warrant a detailed examination of the reasons for this fall, followed by a proper reassessment in light of all available evidence of the extent to which plain packaging is necessary or appropriate to achieve the Objectives.
- 2.34 This continual layering of regulatory measures, without appropriate evaluation as to their effectiveness either individually or collectively is contrary to Better Regulation principles and this Government's desire to simplify and to "reduce the overall volume of new regulation by introducing regulation only as a last resort". No meaningful assessment of the measure considered in the Consultation and the extent to which it is necessary can be made without considering properly if recent regulatory initiatives have been effective and if a new regulatory intervention is, in fact, necessary.

D. INADEQUATE CONSIDERATION OF ALTERNATIVES

2.35 It is a fundamental principle of Better Regulation that adequate consideration should be given to alternatives to achieving the policy-maker's goals. The DH however appears to have pre-determined that plain packaging is the appropriate regulatory solution, contrary to the HM Government's advice that "[g]ood policy making should not start with the solution". As a result, it has failed to give adequate consideration to alternatives that are more targeted, effective and proportionate.

No identification or consideration of Option 3

- 2.36 A proper consultation-stage impact assessment should include a "shortlist of options... with an explanation of the selection process conducted to create the shortlist" in order to "demonstrate that the analysis has not jumped to conclusions". ³⁶ The impact assessment flowchart annexed to the back of HM Government's Impact Assessment Guidance (the *IA Guidance*) indicates that "identification and development of options, initial cost and benefits" should be undertaken before the Consultation stage of a regulatory process. ³⁷
- 2.37 The Consultation and IA, however, begin with the DH's policy 'solution' plain packaging and work backwards only to consider other options if those are raised by responses to the Consultation. The Consultation simply states that Option 3 will be "explored following consultation, if responses to the consultation suggest an alternative approach to reduce the promotional impact of tobacco packaging". Put simply, the DH does not try to identify whether there are less restrictive alternatives to its fundamentally flawed plain packaging proposal.

"Impact Assessment Guidance: When to do an Impact Assessment", paragraph 5: http://www.bis.gov.uk/assets/biscore/better-regulation/docs/i/11-1111-impact-assessment-guidance.pdf. Also see "The Coalition: our programme for government" which states: "There has been the assumption that central government can only change people's behaviour through rules and regulations. Our government will be a much smarter one, shunning the bureaucratic levers of the past and finding intelligent ways to encourage, support and enable people to make better choices for themselves" (May 2010): http://www.cabinetoffice.gov.uk/sites/default/files/resources/coalition programme for government.pdf.

- 2.38 The Consultation thus fails to provide any analysis of alternatives, and their respective costs and benefits, and therefore whether they may represent a more "necessary and proportionate response to the policy issue"³⁹ than depriving legal tobacco products manufacturers of their most valuable assets. In failing to identify and review any alternative to plain packaging, the DH is not in a position to assess, as it must, whether plain packaging is "superior by a clear margin" to other possible measures in achieving the DH's policy objectives while minimising the burdens of so doing. ⁴⁰
- 2.39 To consult only on the most extreme of options is contrary to Better Regulation principles.

Insufficient consideration of Option 1

- 2.40 The Green Book emphasises that a shortlist of options "must always include the 'do minimum' option" and that the "relevant costs and benefits to government and society of all options should be valued, and the net benefits or costs calculated". (Emphasis added.)^{xii} It is incumbent on the DH to analyse the costs and benefits of all options. The IA, however, fails to analyse the costs and benefits involved in Option 1 (the option of avoiding more regulation and retaining the status quo). In other words, it fails to analyse the costs and benefits of the baseline scenario properly (including the expected evolution of the baseline, which reflects both existing trends in the market and previous regulation, such as the display ban).
- 2.41 Without a thorough analysis of Option 1, the Consultation cannot fulfil the objective of assessing plain packaging's supposed additional benefits "over and above those expected to accrue from existing tobacco control initiatives, including legislation to end the open display of tobacco in shops". This undermines the reliability of the conclusion in the IA that "[i]t is anticipated that the results of the Consultation will enable an informed decision to be made on whether or not to proceed with plain packaging". 42
- 2.42 The DH cannot make an informed decision about the appropriateness of plain packaging without having consulted, not just on what possible alternatives might be, but also on the comparative merits (if any) of those alternatives and the evidence in respect of each. When stakeholders including JTI are not given an opportunity either to know about what alternatives are being considered under Option 3, or to comment on them, such a process contravenes fundamental Better Regulation principles. Should the DH nevertheless proceed with proposals for plain packaging, a further consultation must be carried out so that full consideration is given to alternatives arising from the current, preliminary, consultation process.

See the "Green Book – Appraisal and Evaluation in Central Government", available at http://www.hm-treasury.gov.uk/d/green-book complete.pdf, paragraphs 5.7 and 5.8. Further, Box 3.1 of the Green Book provides a best-practice example of a cost benefit analysis, which includes an explicit calculation of the cost and benefit of Option 1. Similarly, the European Commission's Impact Assessment Guidelines (15 January 2009, available at http://ec.europa.eu/governance/impact/commission-guidelines/docs/iag-2009-en.pdf) state, at paragraph 9.1, that, "[f]or all of the options you analyze (including the 'no EU action' option), you need to consider all the relevant positive and negative impacts alongside each other, regardless of whether they are expressed in qualitative, quantitative or monetary terms".

- 2.43 Furthermore, JTI has called for discussions with the DH about JTI and other manufacturers entering into a responsibility deal with the DH. The DH's decision to rule out such a responsibility deal is contrary to fundamental Better Regulation principles which require the Government to demonstrate, before regulating, that "satisfactory outcomes cannot be achieved by alternative, self-regulatory, or non-regulatory, approaches". More fundamentally, however, this demonstrates the inability of the DH to engage in systematic discussion and analysis of measures that will work to achieve its objectives, rather than regulating to pander to supposed public opinion. A responsibility deal is a viable alternative solution to draconian plain packaging proposals and JTI believes it should be considered by the DH instead of further legislative intervention.
- 2.44 There are effective and proportionate alternative solutions. JTI has called for discussion with the DH about its alternative solutions. The failure of the DH to consider such alternative solutions demonstrates again its inability to engage in systematic discussion and analysis of measures that will work to achieve its objectives.

E. INADEQUATE CONSIDERATION OF UNINTENDED CONSEQUENCES

- 2.45 The IA leaves critical questions for example, on the potential impact of plain packaging on illicit trade, price and competition, innovation and brand equity unanswered.
- 2.46 Plain packaging will inevitably have serious implications for intellectual property rights (*IPRs*). However, such implications are inadequately dealt with in the IA and the questions posed by the Consultation do not relate to IPRs.
- 2.47 The principles of Better Regulation require a significantly more thorough regulatory impact assessment before regulatory action can be proposed. The RPC has recognised this hence the IA's 'amber' rating, indicating "areas of concern which should be corrected". The plain packaging proposal cannot be justified at all, and certainly could not be taken forward on the basis of the IA as it currently stands.

F. THE IMPORTANCE OF GOVERNMENT STAKEHOLDERS

- 2.48 A critical Better Regulation requirement is for the DH to determine the views of other government departments and agencies best placed to comment on the likely impact of the proposed regulatory measure, and any unintended consequences which the measure may have. The process is designed to ensure that the regulation is both consistent and targeted only at cases where action is needed. The Consultation and IA have not said whether discussions with the following governmental stakeholders have taken place and this should now be made clear:
- (a) **HM Revenue & Customs (HMRC)** and the **UK Border Agency (UKBA)** should be consulted, as expert opinion suggests that plain packaging will lead to an increase in the illicit trade in tobacco products as explained below in Section 4. This is particularly important given:

- (i) recent successes in combating illicit trade as a result of coordinated efforts between the industry, on the one hand, and HMRC and the UKBA, on the other; and
- (ii) further funding requirements in light of an increase in illicit trade and the need for increased resources for pack authentication;
- (b) **HM Treasury** should be consulted about the cost to the UK taxpayer and public sector in terms of revenue lost as a result of an increase in both illicit trade and legitimate cross-border shopping. Discussions are also needed concerning: (i) the potential job losses within the tobacco industry's UK manufacturing sites; (ii) reductions in economic activity in the UK, which are expected to flow from a plain packaging proposal; and (iii) an increase in resources required to combat the illicit trade in tobacco products;
- (c) with regard to the **Department for Business, Innovation and Skills** (*BIS*), the measures will have negative operational and competition impacts not only on tobacco manufacturers, but also a host of other stakeholders including wholesalers, retailers and suppliers to manufacturers (creative design houses, etc.), many of which are small and medium-sized businesses. As BIS is committed to promoting "competition and stability without impinging on businesses' ability to operate", 45 its involvement in the evaluation of the direct and indirect impacts of the proposal is essential. The WTO dispute that plain packaging is likely to cause will also be of concern to BIS. Further, the lack of adherence to Better Regulation procedures pointed out in this document and the additional imposition of regulatory burdens will be of particular concern to **BIS** and its **Better Regulation Executive**;
- (d) the **UK Intellectual Property Office** (an Executive Agency of **BIS**) should be consulted, as plain packaging will deprive JTI of its most valuable assets its brands and trade marks;
- (e) efforts must be made to address the **Department for International Development,** as plain packaging is likely to all but end product innovation, including in relation to particularly high quality, or specialised, tobacco, and may also lead to some manufacturers lowering quality standards. This could affect those countries which supply high quality tobacco leaf, including developing countries, such as Brazil, India, Tanzania and Zimbabwe;
- (f) given that plain packaging is likely to limit competition, the **OFT/Competition Markets Authority** should be consulted. This is especially the case since the tobacco control measures already in place in the UK have limited the components by which tobacco manufacturers are able to compete;
- (g) Local Government Regulation (*LGR*) must be consulted regarding the difficulties in enforcement and how this might be achieved in light of the current tobacco regulation enforcement strategies. LGR is the body responsible for overseeing local authority regulatory enforcement and related services in the UK. Adjusting local government priorities will also necessitate

discussion with the **Department for Communities and Local Government**; and

(h) the **Scotland Office**, **Northern Ireland Office** and **Wales Office** should be consulted on any proposal to introduce plain packaging because JTI does not believe that plain packaging could be adopted on a devolved basis by the Parliament and Assemblies in Scotland, Wales and Northern Ireland. Nor does JTI believe that, even if plain packaging could be adopted on a devolved basis, it would be appropriate to introduce different packaging requirements for different parts of the UK.

G. THE TIMING OF THE CONSULTATION MAKES NO SENSE

- 2.49 HM Government's Code of Practice on Consultation states: "It is important that consultation takes place when the Government is ready to put sufficient information into the public domain to enable an effective and informed dialogue on the issues being consulted on". The DH is clearly not in a position to put such information forward.
- 2.50 With that in mind, there can be no justification for pre-empting what the actual impacts of plain packaging might be, particularly when:
- (a) the legality of the only plain packaging measure to be adopted in Australia is currently the subject of not one but three different types of challenge (including steps being taken to commence proceedings before the WTO, with a number of countries having called into question the compatibility of such a measure with WTO law);
- (b) similar measures are in parallel being considered by the European Union (the *EU*), so UK taxpayers are currently funding not one but two consultations on a measure which will not work, and which will result in serious unintended consequences. In JTI's view, it is not consistent with EU law for the DH to proceed further whilst EU measures are under active consideration, ⁴⁷ and JTI notes that the European Commission has previously stated that, "[a]ny possible national plain packaging measure would need to be examined in the light of the EU Treaty provisions and other existing EU legislation. The introduction of plain packaging... is being examined... [and] it is premature to prejudge the outcome of the analysis", ⁴⁸
- (c) recent tobacco control measures have yet to be given a chance to work and no holistic review of the effectiveness of the above measures appears to have been attempted;
- (d) the DH has failed to produce reliable evidence since commenting in 2009 that "[n]o studies have been undertaken to show that plain packaging of tobacco would cut smoking uptake among young people or enable those who want to quit to do so";⁴⁹ and
- (e) the IA is, in critical respects, manifestly incomplete and inadequate (see Schedule 1 of this Response).

2.51 Should the DH decide, contrary to JTI's views, to proceed with proposals for plain packaging, a thorough and evidence-based public consultation would need to be carried out in which the DH sets out, for the full consideration of stakeholders, the evidence on the actual impact its proposed regulation would have on smoker behaviour. Mark Prisk MP, Minister for Business and Enterprise, recognised this recently in a letter to an industry stakeholder (a copy of which has been given to JTI), in which he admitted: "If at the end of the consultation we are minded to take 'plain packaging' forward as a policy option the next stage would be to develop detailed proposals. These would then need to be put out for public consultation and that is the point where your concerns [about the detrimental impacts of plain packaging] will need to be properly taken into account". ⁵⁰

3. PLAIN PACKAGING

Introduction

- 3.1 Plain packaging represents an extraordinary and unprecedented deprivation of JTI's most valuable assets its brands and trade marks. It would be manifestly disproportionate, unjustified and unnecessary, and would lead to an infringement of fundamental legal rights and serious and widespread negative effects, including in relation to the illicit trade in tobacco products.
- 3.2 Were plain packaging to be introduced despite all the points made in this Response, it would lay down a precedent for plain packaging of a whole range of consumer products the risk of which is demonstrated by recent consideration (by Parliament's Health Select Committee) of plain packaging for alcohol.
- 3.3 Furthermore, no market in the world has plain packaged tobacco products. As the IA acknowledges, ⁵¹ Australia is the only country which has adopted such legislation, but it has not yet been implemented and is subject to three separate challenges. ^{xiii} There is no mention of plain packaging in the Framework Convention on Tobacco Control (*FCTC*). The non-binding guidelines to the FCTC (the *guidelines*) do not recommend plain packaging, but merely its consideration. ⁵² Indeed, several governments have considered plain packaging, but have rejected it for both the lack of evidence (e.g., as the UK did in 2008/9) and/or for legal reasons (e.g., Lithuania in 2010). ^{xiv}
- 3.4 JTI demonstrates below:
- (a) that there is no reliable evidence, and certainly no "robust and compelling" case, that plain packaging will achieve the Objectives (Section 3);
- (b) the serious and widespread negative effects of a plain packaging measure, including on the illicit trade in tobacco products (Sections 4 and 5); and

Two legal challenges have been brought against the Australian legislation: a challenge before the Australian High Court, alleging that the legislation breaches the Australian Constitution (as an acquisition of property without just terms), and an international arbitration, alleging the legislation breaches the bilateral investment treaty between Australia and Hong Kong. Separately, two countries (Honduras and Ukraine) have taken the first step which would result in a WTO dispute on the basis that the Australian legislation breaches international trade and intellectual property laws.

Judgment is awaited in the Australian High Court challenge, whilst the other sets of legal proceedings are at a more preliminary stage.

In December 2009, a draft law requiring tobacco products to be sold in standard white packages was proposed in Lithuania. In January 2010, the Parliamentary Legal Affairs Committee concluded that the proposed law was likely to contradict the constitutional protection of rights to property and could cause problems in respect of both the international treaty protection of intellectual property and the free movement of goods throughout the EU. On 30 March 2010, a majority of members of the Lithuanian Parliament supported this conclusion. It should be noted that the Committee chose not to rule with respect to property; this apparently reflected the view that the European Commission would consider plain packaging as part of its review of the Tobacco Products Directive.

Australia adopted plain packaging legislation on 1 December 2011. By 1 December 2012, only plain packs will be available for sale in Australia.

(c) the infringement of fundamental legal rights occasioned by a plain packaging measure (Section 6).

NO RELIABLE EVIDENCE THAT PLAIN PACKAGING WILL ACHIEVE THE OBJECTIVES

Packaging is not a predictor of smoking behaviour

- 3.5 Plain packaging is based on a fundamental mischaracterisation of the role of packaging. The Consultation assumes that packaging changes smoking behaviour, particularly of minors. This is wrong and is not supported by the evidence. Plain packaging is not based on, or consistent with, a credible and scientifically rigorous understanding of smoking behaviour. By ignoring the evidence and the Government's own research, the Consultation wrongly assumes that plain packaging will change smoking behaviour.
- 3.6 The need for, and likely effectiveness of, tobacco regulation can only be properly and coherently assessed if it is informed by the best contemporary scientific thinking on the smoking behaviour of adults and minors. In December 2010, JTI responded to the European Commission's Consultation on possible changes to the Tobacco Products Directive, which also addressed plain packaging. Leading experts (notably Professors Steinberg, Dhar and Nowlis) prepared reports, which accompanied JTI's submission, and which gave their independent opinions, on the basis of contemporary scientific thinking, on how the smoking behaviour of adults and minors should best be understood. In JTI's opinion, it flows from these experts' findings that:
- (a) measures to reduce smoking among minors will only be effective if they control minors' ability to obtain tobacco products and remove cigarettes from the social networks of teenagers. Access-based solutions take due account of the fact that minors are *naturally* more prone to risk-taking behaviour than adults. As Professor Steinberg explains, decision-making during adolescence is characterised by a heightened emphasis on rewards over risks; a tendency to focus on the immediate, rather than longer term, consequences of a decision; a susceptibility to peer influence; and weak self-regulation. Minors are well aware of the risks of smoking, but may choose to experiment anyway. Taken together, these factors explain why a psychological profile characterised by sensation-seeking, peer and family influence (i.e., peers and family members who smoke) and the availability of cigarettes are the main risk factors for smoking. Accordingly, measures focused on packaging are unlikely to be effective; and
- (b) **measures directed at adult smoking behaviour** need to target adults' decision-making at the point of consumption in order to be effective, taking due account of the analysis that adults employ when making decisions about risk. They would also need to be more individualised and positively framed, in the light of the triggers to smoking behaviour. Professors Dhar and Nowlis therefore dismiss the likely effectiveness of interventions that reflect the so-called 'traditional model' of consumer decision-making, which is based on the notion that rational consumers will shift their smoking behaviour based on their evaluation of information on the health risks of smoking.

- 3.7 These experts demonstrate that the notion that packaging is a predictor of smoking by minors or minors' initiation is misconceived.
- 3.8 The DH has ignored the significant body of its own evidence on the predictors of smoking: this evidence does not include packaging among the predictors of smoking. In 2008, the FTC Document listed the "predictors of regular smoking among young people" as: 55
- (a) age and sex;
- (b) home environment;
- (c) drug use and drinking alcohol; and
- (d) truancy and exclusion from school.
- 3.9 The FTC Document also notes that; "[s]mokers in the routine and manual occupational grouping take up smoking regularly at a younger age than smokers in other groups. The age at which people started smoking is broadly the same across the socio-economic classifications, with the exception that far more smokers from the routine and manual grouping say they started smoking regularly under the age of 16...". 56
- 3.10 The DH's own previous analysis therefore corroborates the expert evidence on which JTI relies. It is not surprising therefore that the DH cannot provide reliable evidence that plain packaging will achieve its public health objectives, because it misunderstands the role of packaging in smoking behaviour.
- 3.11 Packaging is the means by which adult smokers identify, obtain information about and choose tobacco products, easily and without confusion. Packaging is important because it is one of the essential, and in the UK one of the few remaining, components of brand competition. Distinctive product packaging is fundamental to facilitating inter- and intra-brand^{xv} navigation and competition, and is the primary tool for developing brand equity, innovation and non-price competition. Manufacturers and consumers must be able to identify and distinguish products. This is an essential function of packaging and trade marks. It is incorrect to characterise purchases of tobacco products as 'impulse purchases' since the vast majority of consumers have decided to buy a (specific) tobacco product prior to visiting the retail outlet at which they make that purchase.⁵⁷ Further detail on the role played by tobacco product packaging is contained in JTI's 5 September 2008 response (the *FTC Response*) to the FTC Document.⁵⁸

Plain packaging will not achieve the stated policy Objectives

3.12 The DH must justify the introduction of plain packaging in light of its Objectives, all of which seek to change smoking behaviour. It must provide – in its

Inter-brand is used in this document to refer to navigation and competition between different brands of tobacco product (i.e., Winston and Camel) whereas intra-brand refers to navigation and competition between members of the same brand family (i.e., Winston Blue or Winston Red). See also paragraphs 5.18 to 5.20 of this Response.

own words – "strong and convincing evidence". It did not have sufficient evidence in 2008.⁵⁹ This was confirmed more recently in May 2011.^{xvi} There is still insufficient evidence. **The DH has not put forward any evidence that addresses the impact of plain packaging on actual smoking behaviour**. It acknowledges this, and instead proposes an 'expert panel' to fill the obvious gaps in its evidence base.

- 3.13 JTI discusses below:
- (a) the absence of reliable evidence on smoking behaviour;
- (b) the absence of any reliable evidence that plain packaging will achieve any of the Objectives; and
- (c) the fundamental flaws with the 'expert panel' proposed to fill the gaps.
- 3.14 JTI has commissioned expert analysis by Professor Devinney and Dr Keegan to review the publicly available consumer survey evidence in respect of plain packaging. JTI's views on the evidence are based on the independent opinions expressed by Professor Devinney and Dr Keegan in their reports. Their reports are at Annexes 8 to 12 of this Response.

No evidence on the impact of plain packaging on smoking behaviour

- 3.15 The DH has not put forward any reliable evidence that addresses the impact of plain packaging on actual smoking behaviour. No such evidence is cited in the Consultation. There is no behavioural evidence cited in the IA. The Systematic Review of available evidence addresses different issues, and it finds in any event that the evidence is inconclusive.
- 3.16 First, the Systematic Review does not assess the impact of plain packaging on smoking *behaviour*. The Systematic Review cannot and does not therefore demonstrate that the Objectives will be achieved by plain packaging. The Systematic Review makes this clear on its face. It states that:
- (a) it reviews evidence on plain packaging in order to "inform responses to this Consultation and any subsequent policy making"; 60 and
- (b) its primary aim is "to assess the impact of plain tobacco packaging on the: (i) appeal of the packaging or product; (ii) salience and effectiveness of health warnings; and (iii) perceptions of product strength and harm". 61
- 3.17 Secondly, the authors of the Systematic Review note that the evidence is inconclusive in terms of what if any behavioural changes may occur as a result of plain packaging, stating that:

"findings regarding smoking-related attitudes, beliefs and behaviour from both the surveys and qualitative studies in the review are reliant upon self-

in an email dated 10 May 2011, DH has stated that "there isn't any hard evidence to show that [plain packaging] works". This email was part of the material disclosed on 19 August 2011 pursuant to a FoIA request by Philip Morris International (Ref TO00000633879).

report. Without any form of validation (such as validating reported changes in cigarette consumption) these have quite weak predictive validity. A common argument is that plain packaging research can never truly replicate real market conditions and, as such, the suggested impacts on consumption, cessation and uptake are so far speculative". (Emphasis added.)⁶²

- 3.18 Furthermore, the authors state that "the absence of trials and longitudinal research is the most significant limitation of this review, although one which is impossible to avoid unless the policy is in place in at least one jurisdiction". ⁶³
- 3.19 Not a single study can be pointed to in the Systematic Review which would demonstrate that a plain packaging measure will actually achieve the Objectives. The DH has failed, by its own admission, to establish that there is any reliable evidence on plain packaging and changes to actual smoking behaviour. It concedes that the evidence which does exist is "speculative". 64
- 3.20 The DH recognised in 2008 the limitations in the evidence base, stating that "more needs to be done to develop our understanding of how the packaging of tobacco products influences smoking by both adults and young people". The Systematic Review demonstrates that the evidence remains, at best, "speculative". 66
- 3.21 It is obvious that, as no country has real life experience of plain packaging, no observed evidence will exist as to whether it actually changes smoking behaviour in the wider population and in overall prevalence rates. Australia has adopted relevant legislation on 1 December 2011, which requires that only plain packs will be available for sale by 1 December 2012. Therefore, even if it survives legal challenges, it is not effective until December 2012. In addition, differences between markets may confound comparisons or the transposition of effects.
- 3.22 The IA recognises that "a key difficulty in evaluating this policy... is the lack of quantifiable evidence on the likely impact of standardised packaging". ⁶⁷ But the absence of observed data means that the DH must be even more vigilant to ensure that the available data is the "best available" and "reliable" (i.e., of the requisite quality). It is wrong, in these circumstances, for the DH to rely on an evidence base which is subject to "a number of limitations". ⁶⁸ This is confirmed by Professor Cave who notes that while the absence of observed data may make it necessary to examine other data types, the DH must not compromise on the **quality** of that data:

"What is key, to satisfy better regulation principles, is that the regulator does not compromise as to the quality of the evidence he takes into account. Indeed, the absence of direct evidence as to whether a measure like plain packaging actually 'works', in my opinion, increases the responsibility on the preparer of the RIA to ensure that the evidence relied upon is objectively reliable and of sufficient quality to justify pursuing the measure. The more draconian or intrusive the measure proposed, the greater the burden on the regulator to ensure this is the case. As a result, in the 'first mover' scenario (and in other situations which I consider below), the regulator should be prepared to commission impartial, credible research to inform the impact assessment if the evidence is not available". (Emphasis added.)

- 3.23 Two points are relevant here regarding the quality of the evidence relied upon.
- 3.24 First, the Systematic Review relies only on **attitudinal** consumer research; but it is well established that people are not particularly reliable at self-assessment. Dr Keegan states that "recall reliability is an important methodological consideration" when reviewing the evidence, ⁷⁰ and that "observing what people do is a better predictor of behavior than recording how people respond to questions about what they think they will do, or what they think others will do, or what they report they have done" and, moreover, that "it is well established that consumer recall of past behaviors can be inaccurate, as the time elapsed between the event and the time of reporting can distort respondents' perceptions". This limitation has been acknowledged in the Systematic Review. ^{xvii}
- 3.25 Secondly, good research will seek to try to mitigate the problem of a gap between attitudinal and behavioural data. Professor Devinney speaks to the issue of "attitude-behaviour gap or the difference between 'stated' intentions and 'revealed' or actual purchases" in paragraphs 2.4 and 2.5 of his 2010 report and paragraphs 2.3 and 2.4 of his 2012 report. In noting that plain packaging does not exist anywhere in the world, Professor Devinney states that in such circumstances "researchers must be cognizant of the degree to which the experimental task creates an outcome that can be linked specifically to behaviour". To attempt to reduce the problem of the "attitude-behaviour gap" in consumer research, Professor Devinney states that "good research" will focus on three factors:
- (a) **incentive compatibility** which "addresses the extent to which the methodology used by the researcher allows (or makes) subjects reveal their true behaviour";⁷³
- (b) **inference of salience** which "addresses the degree to which the sheer addition of a factor that would otherwise not be part of the consumer's decision is all of a sudden added into the mix"; 74 and
- (c) **context** which "addresses the degree to which the decisions individuals are being asked to make is outside the context in which it might normally be made". 75
- 3.26 Following Professor Devinney's review of the publicly available consumer survey studies on plain packaging, he concludes that "there is no indication that the studied individuals' attitudes and intentions, as measured, align with their actual or future behaviour" and further that "the studies also fail to provide experimental or situational contexts in which the individual would be applying the decision model that they used when making purchasing decisions". ⁷⁶

Systematic Review, page 87: "Some caution is required in interpreting these findings, as expressed smokingrelated intentions are not always predictive of future smoking behaviour (Ajzen & Madden 1986, Sheeran 2002) and perceptions of the impact of a future policy measure on the behaviour of others are of course subjective".

There is no reliable evidence to support the introduction of plain packaging

- 3.27 Whilst the IA and the Systematic Review provide no observed data, they rely on a wide range of consumer survey studies. Even though the DH found, in 2009, that there was insufficient evidence, the current Consultation relies on the same and other pre-2009 studies, as well as a number of studies produced after 2009. As demonstrated below, none of these consumer surveys can be considered reliable evidence.
- 3.28 JTI believes, on the basis of expert analysis, that there is no reliable evidence (whether in the Consultation, the IA, the Systematic Review or elsewhere) to suggest that banning branded packaging will lead to a change in actual smoking behaviour, either by way of a reduction in smoking uptake by minors or increased smoking cessation among minors or adults.
- 3.29 As noted above, between the two of them, Professor Devinney and Dr Keegan have reviewed the publicly available consumer survey evidence in respect of plain packaging and examined whether the studies constitute reliable evidence that plain packaging will achieve behavioural public health objectives. Their reviews, taken together, included not only the studies cited in the Consultation, the IA and the Systematic Review, but all publicly available consumer survey evidence to date in respect of plain packaging.
- 3.30 Their reviews evaluated the studies against international standards and best practice for consumer survey research. These criteria include:
- (a) examining "the extent to which a study provides valid and generalisable conclusions that align with what an individual would do across a range of contexts", 77 against which Professor Devinney found that "none of the studies were able to provide a "line of sight" between their attitudinal and perceptual measures and actual purchasing behaviour, nor any of the measures of reducing smoking uptake, reducing smoking consumption or increasing smoking cessation…one would have to make an unjustified leap of faith about the importance of the various measures used in these studies to relate them to actual behaviours"; 78
- (b) attempting to "determine what an individual's decision is via the choices they make", 79 against which Professor Devinney found that "none of the studies has either an effective decision model or a structure to estimate that decision model that would allow one to make a valid estimation of the impact of plain packaging"; 80 and
- (c) seeking to "understand the degree to which stated intentions align better with actual behaviour", 81 on which Professor Devinney states that "it is my conclusion that, as in my 2010 Report, none of the studies met enough of the criteria whereby even if their 'stated intention' measures were derived in a valid manner... one could argue that they would provide potentially valid predictions of actual purchasing behaviour". 82

- 3.31 Further, Professor Devinney finds that: (a) in the case of all the studies, there are significant limitations in the structuring of questions, which in many cases assumed knowledge or led the respondent; (b) the sampling frame in the studies varies, implying that none can be used to make predictions about either the general population or the population of minors (both smokers and non-smokers); and (c) the analysis in the studies suffers from significant statistical validity issues. To summarise these points, Professor Devinney provides an overview of each of the studies examined in his 2012 Report and a summary of their limitations against the above criteria. 84
- 3.32 In conclusion, Professor Devinney states that: "it is my expert opinion based on the publicly available consumer surveys and experiments that I have evaluated in this report that they do not provide reliable evidence that plain packaging would be effective in achieving the public policy goals of changing actual smoking behaviour". 85
- 3.33 The Systematic Review, however, states in its Executive Summary that: "there is strong evidence to support the propositions set out in the Framework Convention on Tobacco Control relating to the role of plain packaging in helping reduce smoking rates". ⁸⁶ This statement is deeply flawed:
- (a) The authors of the IA reached a different conclusion. The IA only says that there are "plausible scenarios" under which plain packaging "could be effective" and that there is only a "possible impact" on consumption. 87 This massively departs from the notion that there is "strong evidence".
- (b) Professor Devinney and Dr Keegan show that there is no reliable evidence, as described above.
- (c) On a closer inspection, the Systematic Review itself suggests that the evidence base reviewed is far from "strong". Indeed, its authors acknowledge that "there are a number of limitations with the plain packaging studies found". 88 For example, amongst other concerns, the Systematic Review states that:
 - (i) "individual studies are limited by elements of study design"; 89
 - (ii) "a limitation in relation to study design is that the evidence in the review is largely drawn from correlational studies, which makes it difficult to draw conclusions about expected outcomes. Many of the studies use hypothetical scenarios, and therefore are not truly able to test how individuals would react or behave if plain packaging was introduced"; 90
 - (iii) "Within the correlational studies in the review there are further limitations in that some of the surveys use samples representative of the general population but most do not, and instead use convenience or probability sampling";⁹¹ and
 - (iv) "a further limitation [of the evidence] is that when comparing new packs (in this case plain packs) with those already in the marketplace,

the new packs typically attract a great deal of both favourable and unfavourable attention". Indeed, of the 37 studies reviewed in the Systematic Review, over 20 adopt the methodology of asking respondents to provide their opinions and perceptions on a comparison between a branded pack and a plain pack. Professor Devinney has questioned studies which utilise this experimental design, stating that "[t]he analysis in these studies suffers from significant validity issues...all of these studies jump from attitudinal results relating to intentions and views on "package attractiveness" to policy conclusions as to the veracity of plain packaging as a regulatory initiative. However, none actually test only plain packaging alternatives – which is the purchasing reality consumers would face – nor do they consider features and contexts which influence cigarette purchasing, such as price or availability. Hence, in my view, they are making conclusions based on false comparisons. In addition, none of their analyses deal directly with the key constructs of smoking uptake, reduction and cessation". 92

- (d) Lastly, the reference to the FCTC is inappropriate. The FCTC does not mention plain packaging, and its non-binding guidelines only propose that parties consider it. No evidence at all is cited in the guidelines.
- 3.34 The Systematic Review is forced, in view of the "limitations" of all of the individual studies, to rely upon the consistency demonstrated by the studies. So, it states that "there was a consistency in study findings regarding the potential impacts of plain packaging...this consistency can provide confidence about the observed potential effects of plain packaging". ⁹³ This defies logic and cannot be correct:
- (a) The Systematic Review wrongly presupposes that "consistency" can be used as a proxy for 'correct'. In short, the authors assume that because the study findings appear consistent when taken as a whole, the evidence base must be methodologically sound and reliable (despite the authors' own recognition of the limitations of the individual studies).
- (b) Adding together multiple flawed studies does not make reliable an unreliable study. By way of analogy, students who fail one exam do not have their position improved if they fail multiple exams. The sum cannot, in this case, be more than its constituent parts.
- (c) The study designs are systematically and consistently flawed. The Systematic Review ignores the fact that the findings are consistent because, in Professor Devinney's words, they "apply what are effectively the same, or very fundamentally similar, flawed approaches to the structure of their experiments". 94
- 3.35 Further the Systematic Review is itself subject to serious methodological limitations, which are discussed in more detail in Schedule 2. Reliance on its conclusions is inappropriate.

3.36 In summary, the evidence base for plain packaging is no stronger now than in 2008. There has been no meaningful development of the evidence base since 2008, despite a number of new studies having been published. The evidence base remains insufficient. The DH cannot rely on the existing flawed evidence base to justify plain packaging. 95

The fundamental flaws with the DH's proposed evidence on smoking behaviour

- 3.37 In the absence of a reliable evidence base, the DH has been forced to propose a process for the creation of new evidence to fill the evidence gaps. The proposed 'expert panel' is an outrageous and self-serving means of side-stepping Better Regulation requirements.
- 3.38 The DH proposes to conduct future research with a panel of "internationally-renowned experts on tobacco control policies" seeking their "subjective judgements" on "the likely impact of the introduction of a plain packaging policy for tobacco products on (i) the number of smokers and/or (ii) the number of children trying smoking". The exercise is to elicit a "best guess" estimate and "highest and lowest estimates of prevalence". 97
- 3.39 **First, the proposed selection criteria and process are biased**. They do not represent all relevant stakeholders, are not appropriate and are contrary to fundamental tenets of Better Regulation:
- (a) The 'expert panel' membership appears designed to reach a predetermined result. As it is to consist solely of experts in the area of "tobacco control", by their very nature, the experts in this area are those who are likely already to have entrenched views on plain packaging as a regulatory measure. Many will have written, published or carried out research in this area, potentially including the flawed studies relied upon by the DH.

The process will allow the appointment of experts who are biased and/or have an economic or personal stake in the findings. Such experts will not be able – without contradicting themselves – to reach any conclusion other than that plain packaging will affect prevalence; their only new input will be 'by how much', on which they may have previously expressed a view.

The IA states that "the latter two requirements suggested by Hora and Winterfeldt (impartiality and lack of an economic or personal stake in potential findings) are considered impractical in this area". ⁹⁸ It is indefensible that the DH does not seek objectivity in its 'evidence' gathering, particularly when it intends to rely on such evidence to support its proposal for plain packaging. Simply stating that to control for bias and self-interest is "impractical" demonstrates why the 'expert panel' should not be taken forward, not why fundamental protections should be ignored.

It is revealing that the DH does not mention Hora and Winterfeldt's statement that when considering an expert judgement panel: "a formal nomination process should also be considered. This is particularly important when there is controversy or alternative viewpoints concerning the subject matter to be

treated. Inviting public interest groups as well as professional organizations to submit nominations may ward off later criticism that the experts were chosen from a select pool that shares only one of several possible viewpoints.... In addition, when there are multiple viewpoints, it is important that balance exists among the experts. Without such balance, the true state of uncertainty in a given situation may be significantly understated". 99

- Relevant expert disciplines are omitted. Despite having stated in 2008 that (b) "more needs to be done to develop our understanding of how the packaging of tobacco products influences smoking by both adults and young people", 100 the selection criteria omit expertise in, for example, the field of consumer behaviour, psychology and statistics (to compare against the 'no change' This exclusion of relevant disciplines is contrary to HM Government's Chief Scientific Advisor's guidelines on the choice and selection of experts, which requires Government to draw on a "range of appropriate expert sources" that "should be sufficiently wide to reflect the diversity of opinion among experts in the appropriate field(s) in a balanced way". 101 No explanation has been given as to why the DH ignored a public process in which experts from beyond the DH's pool of known contacts could volunteer to participate. The limited pool from which the experts are drawn is likely to mean that the contemporary scientific thinking on smoking behaviour is ignored, thereby perpetrating the incorrect assumption that packaging changes smoking behaviour.
- (c) **Influencing the experts' opinions**. The proposed process involves sending the experts "a recently commissioned review on the possible impact of plain packaging". If the review is similar to the Systematic Review, this process will bias the experts and inappropriately and improperly pre-determine the results on the basis of a flawed document. As the Systematic Review was, as identified in FoIA disclosure (discussed at paragraph 2.13 above), itself a consequence of the DH requesting evidence presuming that plain packaging will be effective, the risk is multiplied. Given this concern, it is extraordinary that the DH seeks to emphasise the importance of this pre-read.
- (d) Lack of accountability and transparency. The process provides for the anonymous collection of "best guess" estimates. The experts will simply be identified by region. The experts will therefore bear no individual responsibility for the best guesses that they provide, nor will the process allow for third-party verification or evaluation of the experts' guesses. If the experts really are experts, there is no basis for anonymity and no reason to shield their views from scrutiny. This proposal runs counter to the most fundamental elements of Better Regulation: accountability, transparency and objectivity.
- (e) **The approach has no statistical validity**. There is no way to determine if any of the results provided by the experts are valid. All that is suggested in this regard is to "confirm the expert is happy with the final result" and "ask for reasons for the estimates". Ultimately, the result of the expert panel is no more than a pooling of untested and biased opinions.

- 3.40 Secondly, JTI fundamentally disagrees with the DH's proposal to base policy-making on eliciting expert "best guesses" on any quantifiable impacts of plain packaging as a proxy and replacement for actual behavioural data. Individuals' judgements on predicting future behaviour of others are not a reliable proxy for actual behavioural evidence in a public policy context. Indeed, authors who have previously considered the limitations of expert judgement panels have stated that:
- (a) "expert judgments have been worse than those of the simplest statistical models in virtually all domains that have been studied"; 103
- (b) "In nearly every study of experts carried out within the judgment and decision-making approach, experience has been shown to be unrelated to the empirical accuracy of expert judgments";¹⁰⁴
- (c) "People's decision-making behaviour deviates systematically from normative models. Professionals are no exception. Their decision-making shows the same kind of biases as lay people's decision-making.... Motivational and emotional factors can also create biases"; 105 and
- (d) "expert judgments should be used with caution, not to replace 'hard' science". 106
- 3.41 In fact, there exists a wealth of evidence on the 'performance of experts' which shows clearly that experts invariably (and overwhelmingly) underperform statistical models. 107
- 3.42 Despite these warnings, this is exactly the approach that the DH has proposed to adopt. The individuals chosen by the DH are being asked on a phone call for their "best guess estimate" of the likely impact (in percentage terms) of plain packaging on "all smokers and for children trying to smoke" as a substitute for actual behavioural data. Given Better Regulation principles, it cannot be right that the DH seeks to base its policy on a "best guess" given in a telephone conversation.
- 3.43 Professor Cave makes two further important points in his 2010 Report of relevance here. Where it is necessary for the regulator to commission research because, for example, no real life data exists and/or because the existing evidence base is non-existent or poor:
- (a) it would normally be appropriate for the regulator to await the research it has commissioned before implementing the measure in respect of which the research is being commissioned; 110 and
- (b) it would be consistent with the Better Regulation principle of transparency for the regulator to publish that evidence once it is available, so that it can be reviewed and considered by others.¹¹¹
- 3.44 In summary, the DH's proposal to cobble together expert judgements to try to create quantitative data is a last refuge for a desperate policy-maker that lacks any reliable evidence to support its preferred policy. The evidence should drive policy, not the other way around.

The other 'reasons' for seeking to mandate plain packaging are flawed

- 3.45 In addition to identifying the Objectives for a plain packaging measure, the Consultation identifies the Mechanisms by which the Objectives might be achieved, namely:
- (a) "reducing the appeal of tobacco products to consumers";
- (b) "increasing the effectiveness of health warnings on the packaging of tobacco products";
- (c) "reducing the ability of tobacco packaging to mislead consumers about the harmful effects of smoking"; and
- (d) "having a positive effect on smoking-related attitudes, beliefs, intentions and behaviours, particularly among children and young people".
- 3.46 These Mechanisms are not Objectives. Their sole purpose appears to be to construct alternative issues that the DH considers might be addressed by plain packaging. This simply diverts attention away from the real issues, namely that the DH misunderstands the role of packaging in smoking behaviour and decision-making, and that the DH has failed to provide any reliable evidence on the impact of plain packaging on smoking behaviour.
- 3.47 None of the Mechanisms justify plain packaging, whether considered individually or taken as a whole. As explained further below, the Mechanisms are: illegitimate as public policy objectives; insufficiently articulated and evidenced; insufficiently capable of changing smoker behaviour; and unnecessarily duplicative of existing regulation.

"Appeal" is not a proper policy objective

- 3.48 The Mechanism referring to reducing "appeal" is reminiscent of the references to "attractive packaging" in the FTC Document.
- 3.49 In the same way as reducing 'attractiveness' is a flawed policy goal, reducing the "appeal" of tobacco products to consumers *per se* is not, and cannot be, a self-standing justification for tobacco regulation. It is an amorphous and vague concept. It fails established 'issue definition' criteria: it is lacking in any evidential foundation and is inherently uncertain and arbitrary. It simply acts as an umbrella term, and the DH must identify, articulate clearly and assess the evidence against the underlying public policy objective(s). This Mechanism construct cannot advance the plain packaging debate or justify its introduction.
- 3.50 The DH also fails to assess whether plain packaging may be seen by minors as rebellious, thereby undermining the Objectives. This issue was raised by the DH in the FTC Document, 113 but has not been evaluated in the Consultation or IA.

No evidence that increasing the prominence of health warnings will affect smoking behaviour

- 3.51 While there is already a very high level of awareness of the health risks of smoking in the UK^{xviii}, JTI supports the continued provision of information to consumers about the health risks of smoking in order to ensure that smokers continue to be reminded of those risks. However, increasing the prominence or salience of health warnings on tobacco packaging is not, of itself, a legitimate public policy goal capable of justifying a plain packs measure. The Consultation's Objectives are to change smoking behaviour; this Mechanism does not relate to behavioural change.
- 3.52 The relevant section of the IA (paragraphs 26 to 28) does not even attempt to claim that plain packaging would change smoking behaviour via this Mechanism. Indeed, the evidence cited comprises two studies from 1995 (which would have been available to the DH in its 2008 consultation which concluded that the evidence was insufficient) and one "unpublished manuscript" from 2011.
- 3.53 'Noticing' something, particularly something one knows already such as a health warning on a tobacco product does not necessarily translate into a change in actual smoking behaviour by consumer survey respondents. The DH has not demonstrated convincingly that plain packaging would enhance the 'visibility', 'prominence' or 'salience' of health warnings; and the DH has not even attempted to demonstrate that, via this Mechanism, plain packaging would actually result in changes to smoking behaviour (such as reducing smoking uptake by minors). This Mechanism cannot be used to fill the DH's evidential gap, and justify the introduction of plain packaging.

Tobacco packaging does not mislead consumers

- 3.54 Existing law prevents the misleading use of packaging for consumer goods, including tobacco products.¹¹⁴ Indeed, there are specific rules prohibiting the use of misleading terms on tobacco product packaging.¹¹⁵
- 3.55 Despite this, the Consultation identifies a Mechanism to "reduce the ability of tobacco packaging to mislead consumers about the harmful effects of smoking". This is repeated like a mantra throughout the IA, but there is no explanation of how current tobacco packaging is said to mislead consumers, or indeed why the existing law is not adequate to address such issues. No basis at all has been put forward to support this Mechanism.
- 3.56 Consumers, in fact, take smoking-related health messages from a variety of different sources and media, including on-pack health warnings, and are well aware of the health risks of smoking. In 2011, JTI created a website,

Indeed the Public Health Minister has recently stated that the UK has passed "a great deal of legislation and run a lot of public health campaigns [to inform the public of the harms of smoking] and no one is in doubt" to the extent that she believed that "96% of the population agree that smoking harms your health". See "Written evidence from the Department of Health: Government's Alcohol Strategy", Health Committee, Uncorrected Transcript of Oral Evidence, Parliament, 12 June 2012, available at http://www.publications.parliament.uk/pa/cm201213/cmselect/cmhealth/uc132-ii/uc13201 htm.

<u>www.nosafecigarette.com</u>, with information to reinforce the message that no cigarette is safe, and to clarify any misconceptions that consumers may have.

3.57 It is simply not necessary or proportionate to propose plain packaging in light of this Mechanism.

Plain packaging will not affect smoking-related attitudes, beliefs, intentions and behaviours

- 3.58 This Mechanism is an imprecise mish-mash of issues. The Consultation proposes plain packaging to change smoking behaviour, for which there is no reliable evidence. This Mechanism introduces extended notions of "smoking-related attitudes, beliefs [and] intentions". Neither the Consultation nor the IA explain what this is intended to address. They seem to proceed on the basis that plain packaging will affect smoking-related attitudes, beliefs and intentions, with the implication that this will change behaviours.
- 3.59 Such an approach is not based on, or consistent with, a credible and scientifically rigorous understanding of smoking behaviour, because it incorrectly assumes, first, that tobacco packaging is a predictor of smoking initiation whether amongst adults or minors, and secondly, that more information will lead to a change in behaviour. Expert evidence demonstrates that this is not the case, for the reasons set out by Professors Steinberg, Nowlis and Dhar, noted above at paragraph 3.6.
- 3.60 If this Mechanism is intended to portray a goal of 'denormalising' smokers, 116 this is not, and cannot be, a self-standing objective that can justify plain packaging. It is wrong to seek to discriminate against, stigmatise or ostracise existing adult smokers, or to treat the purchase or use of tobacco, as 'abnormal', 'unacceptable' or 'tainted'. As a policy, it runs counter to the hallmarks of the UK as a democratic society (notably pluralism, tolerance and broadmindedness), lacks any evidential foundation and is arbitrary.

4. PLAIN PACKAGING IMPEDES AND RESTRICTS LAWFUL ACTIVITY, WHILST FACILITATING ILLEGAL ACTIVITIES

- 4.1 The Consultation and the IA have not properly considered the range of serious consequences which would result from the adoption of plain packaging. Given that its adverse effects are manifest, and in the absence of reliable evidence that it will achieve the Objectives, plain packaging is unnecessary, inappropriate, disproportionate and would breach JTI's fundamental rights.
- 4.2 Plain packaging for tobacco products would lead to a series of negative and undesirable consequences, including:
- (a) worsening the illicit trade in tobacco products;
- (b) negative effects on consumers;
- (c) negative effects on the tobacco retail trade and connected industries;
- (d) signalling that the UK is not 'open for business', as it turns its back on intellectual property and investment protection;
- (e) the erosion of the brand equity that has been built up and which is currently attributable to JTI's brands, and a disproportionate impact on JTI's premium brands; and
- (f) the serious and unnecessary damage to the legitimate economic interests of tobacco manufacturers and competition in the UK tobacco sector.
- 4.3 The impact of plain packaging on illicit tobacco trade is explored first in this section and the other consequences (listed (b) to (f) above) are discussed in Section 5 below.

WORSENING THE ILLICIT TRADE IN TOBACCO PRODUCTSXIX

- 4.4 Plain packaging will worsen the trade in illicit tobacco products in the UK. JTI's views on this point are based on JTI's own industry expertise and on the expert opinions contained in Professors Zimmerman and Chaudhry's Report, attached at Annex 3.
- 4.5 The UK already has a significant illicit trade problem. This is clear from the IA itself, which notes in Table 3 (using conservative assumptions) that, while the illicit trade in tobacco products has declined in recent years, 10% of the market for cigarettes, and 46% of the market for RYO, is still illicit (HMRC's current upper

For the purposes of this paper, JTI is treating the terms 'counterfeit' and 'contraband' to have the following meanings: (a) counterfeit cigarettes are cigarettes that bear the trade marks of a genuine cigarette manufacturer (such as JTI) but which are, in fact, manufactured by a third party without the consent of the genuine manufacturer; and (b) contraband cigarettes are cigarettes that have been imported into, distributed in, or sold in a market in violation of the applicable tax, duty or other fiscal laws of that market. The definition of 'illicit whites' (or 'cheap whites') varies, and determining when this product becomes illicit in its supply chain is controversial – there is no standard agreement among various authorities. See Professors Zimmerman and Chaudhry's Report, paragraphs 153 to 159 (Annex 3).

estimates are that 16% of the market for cigarettes, and 50% of the market for RYO, are illicit). HM Treasury already loses up to £3.1 billion a year from the illicit trade in tobacco products. The IA also notes the significant consequences of the problem for the UK Exchequer: "a one percentage point increase in the tax gap for cigarettes would be equivalent to around a £90m duty loss". 119

4.6 HM Government has previously recognised the seriousness of the illicit trade problem. Justine Greening MP (then Economic Secretary to the Treasury) and Damian Green MP (the Minister of State for Immigration, Home Office) wrote the following foreword to the HMRC/UKBA report "Tackling Tobacco Smuggling – building on our success":

"The Government believes that tobacco smuggling must be tackled head on. Tobacco fraud [deprives] the general public of revenue to fund vital public services that support us all. The availability of illegal tobacco products undermines public health objectives and impacts on the health of both individuals and wider communities; circumventing health labelling requirements and age of sale restrictions.... The smuggling of cigarettes and [RYO] is also a key business for organised criminal gangs who use the proceeds of this crime to fund the smuggling of drugs, weapons and also human beings. It harms the overwhelming majority of law-abiding businesses who sell tobacco products legally, diverting revenues from retailers all over the country". 120

- 4.7 A further exacerbating factor for the illicit tobacco trade in the UK is illegal activity taking place across the border between the UK and Ireland. As Professors Zimmerman and Chaudhry explain, it has long been recognised that Ireland and the border between Northern Ireland and Ireland is used as a gateway for smuggling into the UK. HMRC has also noted that the border is used by criminal gangs to conceal their activities and disrupt law enforcement action, with the continuing security situation deliberately exploited to hinder law enforcement efforts. 122
- 4.8 The Consultation and the IA recognise the risk that the illicit trade problem will be made worse by the introduction of plain packaging, stating that although "it is hard to predict the potential impact on the complex and dynamic nature of the illicit trade in contraband and counterfeit tobacco", "there is a risk that plain tobacco packaging may lead to some reversal of [the existing downward trend in the illicit trade in tobacco products]". The IA also notes that "it may be argued that plain tobacco packaging would be easier and cheaper to copy, so increasing the supply of illicit tobacco". ¹²⁵
- 4.9 The Consultation and the IA do not address this issue in any more detail. Nor do they attempt to analyse meaningfully the impact of plain packaging on the illicit trade in tobacco products. This is a hugely significant omission in light of the accepted size of the problem in the UK, and its serious negative impacts and societal consequences. Given this, JTI sets out below:
- (a) examples of the measures it has taken to address illicit trade;
- (b) its position on illicit trade; and

(c) informed by the work of Professors Zimmerman and Chaudhry, the impact of a plain packaging proposal on illicit trade.

JTI'S POSITION ON THE ILLICIT TRADE IN TOBACCO PRODUCTS

- 4.10 JTI's position on the illicit trade in tobacco products is clear and unequivocal. We take a zero-tolerance approach to illicit trade: it damages our business and undermines our brands. JTI cooperates fully with governments, regulators and law enforcement agencies in the fight against the illicit trade of tobacco, including consulting on effective ways to reduce smuggling and counterfeiting. Our position is summarised below and set out in more detail on www.jti.com:
- (a) Governments should be encouraged to adopt **comprehensive strategies to tackle cigarette smuggling and product counterfeiting**, which causes substantial losses to governments and industry stakeholders. Only governments can take the lead in the fight against illicit trade, but the legitimate industry has an essential support role to play. Cooperation is vital, as neither industry nor governments can solve this problem on their own.
- (b) The FCTC Anti Illicit Trade Protocol¹²⁶ the text of which was agreed on 4 April 2012 for adoption in November 2012 is a positive measure to raise awareness of this growing global phenomenon and provide guidance to member countries on policies and approaches to fight against illicit trade. 127
- (c) HM Government's **tobacco taxation** policy **increases the incentives for those involved in the illicit trade** of tobacco products in the UK. Illicit trade continues to be encouraged by: (i) high retail prices driven by the UK's high rates of taxation on tobacco products, which are some of the highest rates in the world; and (ii) the potential profits these policy decisions provide for those involved in the contraband trade.

High tobacco taxation rates and/or tax rates significantly higher than those of neighbouring countries inevitably encourage contraband inflows as smuggling is driven by consumer demand for a cheaper, or banned, product.

The HM Government's tax policy has created a situation where UK consumers will continue either to avoid UK tax by buying cigarettes legally abroad, or to evade tax altogether by buying illicit cigarettes from illegal sources, whether manufactured legitimately or counterfeit.

- (d) Tackling illicit trade is critical if HM Government is to **discourage minors** from taking up smoking and encourage people to quit smoking, as they would be seriously impacted upon by any regulatory measures that have the unintended consequences of increasing the availability of lower-priced tobacco products. 128
- (e) No regulatory action should be taken by HM Government which is at odds with the objectives of EU law in the context of the enforcement of intellectual property rights and illicit trade (namely, that effective means of enforcing such rights are of paramount importance for the success of the

internal market and infringements of intellectual property rights are increasingly linked to organised crime). 129

4.11 As Professors Zimmerman and Chaudhry state: "The illicit trade in tobacco products is a global problem that requires a multi-level response. Therefore, collaboration at the national, regional, and international level between regulators (who set tobacco control and excise measures), enforcement agencies, and those who operate within the legitimate product supply chain is critical to tackling this problem". ¹³⁰

MEASURES TAKEN BY JTI TO ADDRESS THE ILLICIT TRADE

- 4.12 JTI has been working with individual governments, the EU and several anti-counterfeit associations around the world. At the European level, the Head of Unit Customs II in the European Commission Anti-Fraud Office (*OLAF*) commented, in the context of the Cooperation Agreement between JTI and the EU Member States, that OLAF's "excellent working relationship with JTI has delivered tangible results". Further, the UK Economic Secretary to the Treasury has stated in relation to the anti-contraband and anti-counterfeit agreements between EU Member States and the major tobacco manufacturers: "These agreements are an important step forward in the fight against tobacco smuggling. Signing them sends a clear and consistent signal that we are working in step with the EU, other member states and tobacco manufacturers to tackle the illicit trade in tobacco products". 132
- 4.13 JTI has always offered its full cooperation in the battle against smuggling, and participated in a number of public and industry programmes aimed at preventing all types of contraband. HMRC, for instance, has acknowledged the success of Memoranda of Understanding (*MoU*) regarding government-industry cooperation and noted that "the MOUs set out a framework which has resulted in the incidence of UK-manufactured cigarettes being smuggled into the UK falling markedly". The UK Economic Secretary to the Treasury recently confirmed that HMRC and UKBA will "continue to work with the industry establishing new working groups, identifying and addressing intelligence gaps, developing a collective understanding of the illicit market in the UK and sharing insights into consumer and retail education". ¹³⁴
- 4.14 JTI is disappointed that the Consultation fails to acknowledge the measures it and other industry members have taken to address illicit trade issues. The specific measures taken are summarised at http://www.jti.com/how-we-do-business/anti-illicit-trade/our-programs/.
- 4.15 Illicit trade in tobacco products is an issue that needs to be addressed through constructive partnership between the industry, governments and public authorities. The DH's failure to consider such government-industry cooperation initiatives is particularly worrying given the concern expressed by Professors Zimmerman and Chaudhry about the potential of plain packaging to undermine international and UK-specific efforts to tackle the illicit tobacco trade. ¹³⁵

THE IMPACT OF PLAIN PACKAGING ON THE ILLICIT TRADE IN TOBACCO PRODUCTS

- 4.16 The expert opinion of Professors Zimmerman and Chaudhry is that plain packaging "will worsen the illicit trade in tobacco products". ¹³⁶ JTI shares this view. In summary, JTI is extremely concerned that mandating plain packaging will have the following negative effects.
- 4.17 It will facilitate the manufacture of counterfeit products. Sophisticated printing technologies deter counterfeiting. They increase the complexity entailed in producing counterfeit goods, based upon techniques that can be implemented effectively by legitimate manufacturers on an industrial scale. However, such techniques are far less economic and more complex to implement on a smaller scale (for example, in a clandestine environment rather than a legitimate factory set-up). Professors Zimmerman and Chaudhry note that: "Currently packaging that is complex or innovative acts as a deterrent to counterfeiters of tobacco products since keeping up with the evolving packaging of genuine product is an expensive and time-consuming process". Professors Zimmerman and Chaudhry also note that plain packaging regulation which is publicly available means that: "Illicit traders are effectively given a blueprint of 'how to make the pack'... in contrast to the current practice where design specifications and colors are deliberately kept confidential in order to deter counterfeiters". ¹³⁸
- 4.18 It will remove key cost constraints for counterfeiters, as each pack is essentially the same. Once a counterfeiter has mastered the UK plain packaging design for, for example, Benson & Hedges, very few design alterations are needed to this master design to produce counterfeit plain packaging versions of each and every other pack sold in the UK market. Professors Zimmerman and Chaudhry observe that: "once one plain pack brand is faked, the counterfeiter can reproduce packaging of each brand on the market with minimum effort because the only difference is the 'brand and variant names' that appear in the same font/size' and that "[plain packaging] may encourage new entrants to the lucrative business of counterfeiting cigarette packs since the costs and barriers of getting into this business will be reduced". 139
- 4.19 It will crystallise pack design, which will benefit counterfeiters. Legitimate manufacturers would be denied the opportunity to innovate and compete through packaging, something that is standard industry practice for all manufacturers of Fast Moving Consumer Goods (*FMCG*), including JTI. As a result, counterfeiters would only need to meet a government-mandated design, rather than having to keep up with manufacturers' evolving packaging innovations and developments. In this way, plain packaging would, again, effectively reduce the burden on counterfeiters and open the market to new ones. Professors Zimmerman and Chaudhry note that, "the static packaging design means no additional investment is necessary until further change in law. As a consequence, counterfeiters will need to meet this static design only, rather than having to keep up with the manufacturers' evolving packaging innovations and developments". 140
- 4.20 Notwithstanding reductions in the cost of counterfeiting plain packs, it will result in the continued creation of branded packs by counterfeiters, with

branding which the brand owner cannot use. JTI is concerned that some counterfeiters will continue to fake packs using existing, branded, pack designs where plain packaging is mandated. In this way, they will 'adopt' the brand imagery that legitimate manufacturers would no longer be allowed to use. This will be assisted by the fact that:

- (a) consumers may be expected to assume (or led to believe) that these branded counterfeit packs are not 'fake', but have been produced in jurisdictions where plain packaging had not been introduced. This concern is supported by existing evidence that counterfeiters rely on such assumptions to increase the credibility of their counterfeit product by deliberately manufacturing packs for sale in the UK which replicate the mandatory health warnings used in other EU markets. Professors Zimmerman and Chaudhry explain that nimble illicit traders do not confine themselves to only engaging in one type of illicit trade, but have "proven their ability to recalibrate their product offerings depending on changing regulatory, tax, and economic circumstances", offering a whole portfolio of products; 142 and
- (b) some smokers will look to buy the branded packs familiar to them, regardless of the plain packaging measure.
- 4.21 In this way, the imposition of plain packaging would create an opportunity for the counterfeit industry to:
- (a) expropriate manufacturers' branding;
- (b) perversely, charge a premium for this fake product; and
- (c) shift sales volumes away from legitimate manufacturers. 143
- 4.22 **It will increase the trade in 'illicit whites'**. As described at paragraphs 153 to 159 of Professors Zimmerman and Chaudhry's Report, 'illicit whites', which HMRC defines as "cigarettes manufactured for the sole purpose of being smuggled into and sold illegally in another market', ¹⁴⁴ make up a significant, and growing, share of the market for illicit tobacco products in the UK. JTI is concerned that plain packaging would facilitate this trade, a risk identified by Professors Zimmerman and Chaudhry. ¹⁴⁵ In JTI's view, it is inevitable that such products would continue to use branded packaging, even in the face of a plain packs restriction in the UK, given that certain consumers are likely to want to continue to obtain the existing branded packs familiar to them.
- 4.23 **It will increase the trade in contraband tobacco products** (i.e., genuine products smuggled from abroad). As smokers seek out the familiar, JTI considers that it is likely that some of them will turn to contraband products in the same way as they may do toward 'illicit whites' and branded counterfeits (discussed above). Professors Zimmerman and Chaudhry conclude that, "[t]he contraband market is also likely to benefit from the opportunities introduced by plain packaging". 147
- 4.24 It will restrict the ability of consumers to identify counterfeit product. Consumers' ability to identify counterfeit product would be diminished by plain

packaging as pack design is one of the means by which consumers can assess whether they have purchased a genuine or counterfeit product.¹⁴⁸ This undermines one of the essential functions of a trade mark, which – as explained below – is to guarantee the identity of origin of the goods so that the consumer can, without possibility of confusion, distinguish the goods from others. Reducing the ability to carry out this visual authentication is likely to:

- (a) undermine consumers' ability to identify counterfeit product;
- (b) reduce the likelihood that suspicious product would be rejected by them; and
- (c) result in fewer counterfeits being identified and fewer complaints about fake products being made to manufacturers and enforcement authorities.
- 4.25 Consumers' perception of product quality is likely to be negatively influenced where because they are unable to identify a product is counterfeit from its packaging they believe they are smoking a genuine product when, in fact, they are smoking a poor quality counterfeit.^{xx} This could further erode the equity of legal brands.
- It will complicate regulator investigations/prosecutions, requiring more resources to be expended on them. A key investigative tool for UK enforcement agencies is the ability to carry out forensic analysis of counterfeit tobacco packaging to determine its source. As Professors Zimmerman and Chaudhry state: "Currently, a number of elements of the pack (particularly the color, embossing, and brand font) can be analyzed to assess the authenticity of a tobacco product. Consumers and nonspecialist police officers and customs officials may be able to detect that certain packs are fake because of specific sheens or shades of the color of the packaging or spelling mistakes. Retailers may also rely on such visual cues to ensure authenticity. These cues are also used by the genuine manufacturer and specialists within law enforcement to determine authenticity... In a plain packaging environment with pack design specifications mandated by the government, a number of these means of authentication will no longer be available. In our opinion, this could increase difficulties for retailers and many law enforcement officers who rely on the most obvious visual cues. Further, while manufacturers of genuine product will continue to possess the expertise and resources needed to determine the authenticity of their own product, it is likely that even these industry experts (who assist enforcement agencies in their forensic investigation and specialists within law enforcement) may have to resort to more resource-intensive and time-consuming tools of verification in a plain packaging environment". 149 (Emphasis added.)
- 4.27 As Professors Zimmerman and Chaudhry point out, complex health warnings or tax stamps will not be an effective deterrent to counterfeiting these much simpler packs. Such 'anti-counterfeiting markings' are easily faked and counterfeiters generally only do enough to "fool the consumer". Nor are 'track and trace' requirements the answer. These apply only to manufacturers of genuine product (and even then, not all of them). 151

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After unknowingly smoking a counterfeit product, a consumer might lay fault at the door of the legitimate brand owner, if the cigarette is of lower than expected quality.

- 4.28 It may impair the ability of JTI to bring infringement action. As explained at paragraphs 6.18(c) to 6.18(f) below, JTI has serious concerns that plain packaging may reduce its ability to take action in the UK against third parties trading in illicit tobacco products which use JTI's trade marks without consent.
- 4.29 JTI notes that many other organisations share the views expressed above. Most notably, IP Australia, an agency of the Australian government which administers and advises on intellectual property issues, expressed the view that plain packaging will make it easier for counterfeit products to be produced and would make it difficult to readily identify them. ¹⁵²
- 4.30 To the extent that plain packaging facilitates the trade in counterfeit and/or contraband cigarettes and risks undoing much of the progress made in tackling this trade, Professors Zimmerman and Chaudhry note that plain packaging is "highly likely to aggravate the existing negative impacts of the already serious and socially damaging trade in illicit tobacco". In particular, JTI believes that, in this way, plain packaging will:
- undermine the FCTC's anti-illicit trade objectives, as well as the UK's stated aim of using pricing as a means of tobacco control regulation. Those conducting illicit trade in tobacco products are unlikely to be concerned about who they sell their products to. As black market tobacco products are often more accessible to those underage, and those from low income groups, plain packaging also risks undermining the key objective of reducing smoking by minors and those groups; xxiii
- (b) facilitate the growth of the underground economy, thus normalising criminal behaviour and undermining sustainable growth;
- (c) deprive HM Government of tobacco excise revenues that are simply redirected to windfall profits for organised criminal gangs;
- (d) increase the risk to consumers, because of their reduced ability to tell the difference between genuine and illicit product. Regulators and public health officials in the UK have repeatedly expressed the concern that smokers could be exposed to greater health risks by consuming an illicit product; ¹⁵³ and
- (e) cause significant losses to legitimate business, including retailers (see paragraphs 5.3 to 5.8 below).

Professors Zimmerman and Chaudhry's Report, paragraph 432. JTI set out its detailed view on these points in the FTC Response, and notes that similar views are shared by Professors Zimmerman and Chaudhry.

[&]quot;Poorer people are more likely to be tempted by cheaper prices, and access to smuggled tobacco therefore undermines efforts to quit smoking, exacerbating health inequalities. Research commissioned by [Action on Smoking and Health (ASH)] found that one in four of the poorest smokers buy smuggled tobacco compared to one in eight of the most affluent". "Tobacco Smuggling", ASH (April 2011), page 3, accessed at http://ash.org.uk/files/documents/ASH 122.pdf.

THE IMPACT ON LEGITIMATE CROSS-BORDER SHOPPING

4.31 The Consultation asks whether a plain packaging measure will have implications for legitimate cross-border shopping. In JTI's view, plain packaging is likely to increase the amount of tobacco products consumed in the UK that are legitimately purchased overseas and imported (i.e., imported in compliance with applicable duty-free limits and for personal consumption). As Professors Zimmerman and Chaudhry note: "the search for familiar branded packs [acts] as an added incentive to the price benefits of buying packs overseas". ¹⁵⁴ The potentially serious consequences of such an increase are acknowledged in the Consultation itself: "a one percentage point increase in the market share of non UK duty paid cigarettes would cost around £90 million in lost revenue". ¹⁵⁵

5. OTHER NEGATIVE CONSEQUENCES OF PLAIN PACKAGING

NEGATIVE EFFECTS ON CONSUMERS

5.1 As the Prime Minister has recognised, adults should be treated like adults and given "more responsibility over their lives". That is one of the hallmarks of the tolerant, broad-minded and pluralist society which the UK believes itself to be. Plain packaging removes the choice of adult smokers to choose branded product. It removes and restricts adult choices around a legal product.

5.2 In addition:

- (a) it will make consumers' ability to choose between brands by reference to their particular features more difficult. As the British Brands Group highlight, "[b]randing does... help consumers to understand differences between products, to distinguish quickly between them and to buy with confidence. Branding is also crucial to the working of markets, encouraging producers to invest in and compete on quality, new and better products and strong reputations". 157
- (b) it may lead to consumer confusion, as immediate recognition of brands by consumers can no longer be done by reference to the overall 'get-up' of the brand, but only by reading the brand name; and
- (c) the negative effects on competition of plain packaging explored below will reduce consumer choice, and will be economically detrimental to consumers.

IMPACT ON RETAILERS AND CONNECTED INDUSTRIES

Retailers

5.3 JTI believes that retailers would suffer a fourfold negative impact as a result of the introduction of plain packaging.

- (a) First, transaction times will increase as visual pack recognition will be more difficult for retailers when the gantry is opened to serve a customer. The IA is wrong to assert that transaction times for retailers will decrease. A study from Australia prepared for the Alliance of Australian Retailers in relation to the plain packaging legislation, which was introduced in Australia after a display ban was already in place, indicates that transaction times will increase for smaller retailers in particular. 158
- (b) Secondly, the same Australian report suggests that as a result of the increase in transaction times, a plain packaging measure is likely to result in a 'channel shift' from small to large retailers, negatively affecting small retailers already struggling as a result of the current economic climate. As tobacco products are a key driver of 'footfall' (and so of sales of other products) for many (particularly smaller) retailers, xxiii channel shift consequent on plain packaging

As the Scottish Government noted during the passage of the Tobacco and Primary Services (Scotland) Bill on 8 June 2010, "[w]e know from extensive consultation with small tobacco retailers that footfall from customers

- is likely to lead to a significant loss of turnover, profit and therefore viability for many smaller retailers. As tobacco products make up a significant proportion of the turnover of many smaller retailers, plain packaging may have significant cash-flow and credit implications, particularly important in the current economic (and bank lending) climate.
- (c) Thirdly, increased downtrading from premium to value products a risk identified by Dr Lilico and discussed below at 5.16 may result in lower margins for retailers.
- (d) Fourthly, retailers, particularly small retailers, are also likely to be negatively affected by any growth in the illicit tobacco trade that will result from a plain packaging measure. JTI notes that a recent campaign by Trading Standards warned retailers of the risks of illicit tobacco on their business: "Tobacco and alcohol smuggling creates a cheap and unregulated supply chain operated by criminals. This damages honest business, whose trade is reduced when smugglers undercut them by evading tax". 159

Connected industries and the product supply chain

- Plain packaging will undermine any future investment and innovation by the tobacco sector in packaging, and this will have severely detrimental economic impacts on numerous service industries, including pack designers (discussed further in the paragraph below), pack manufacturers and printing and ink suppliers. To put this in context, a 2012 report estimates 66,000 jobs among suppliers, wholesalers, distributors and retailers were dependent on the UK tobacco industry. 160
- 5.5 For instance, JTI accounts for approximately 75% of the business of one of the UK-based packaging/design agencies it uses. The agency has raised the concern that the loss of JTI's business due to plain packaging "would directly affect [its] business" and force the agency to "drastically cut back on [its] staffing". The agency's loss of business will have knock-on effects as well. By way of example, JTI understands that the agency employs a specialist printer to produce the mock-up packs and that the printer is dependent on the work that is generated by JTI. Further detail is set out in Nude Brands' (one of the packaging/design agencies JTI uses) submission to the FTC Document.
- 5.6 A number of major manufacturing businesses that supply tobacco packaging materials have raised the concern that plain packaging will significantly undermine their legitimate economic interests as they have "invested heavily over the years to meet the needs of the tobacco industry, including the regulatory requirements directed by Government. That investment has been both financial and in the development of a skilled workforce, processes of innovation and a high level of manufacturing competence. The introduction of plain packaging would negate the benefits of the investment that has been made". 162

- 5.7 The implications of requiring plain packaging, in terms of the serious and unnecessary damage to the legitimate economic interests of tobacco manufacturers, their connected industries and indirect and multiplier effects, are discussed further at Section 7 of Dr Lilico's 2008 Report.
- 5.8 Plain packaging would also cause significant negative effects on wholesalers. Faced with a channel shift from small retailers (who do use wholesalers) to larger retailers (who do not), their profits are likely to be affected.

DIMINISHED CONTRIBUTION BY JTI TO THE ECONOMY AND SIGNALLING THAT THE UK IS NOT 'OPEN FOR BUSINESS'

- 5.9 In addition to the effects on consumers and participants in the tobacco supply chain, discussed above, any change to the packaging of JTI's products that is required as a result of plain packaging is likely to lead to significant job losses and reductions in income and economic activity in the UK on the basis of:
- (a) 'downtrading' from premium to cheaper legal tobacco products; and
- (b) a shift from the legitimate to the illicit trade.
- 5.10 A recent report estimates that the tobacco industry directly employs 5,700 people in the UK, at a median wage (£727/week) significantly higher than that of the UK manufacturing sector (£479/week) and the average of all UK employees (£404/week). Tax revenue from tobacco contributed £12.1 billion in tax year 2011/12. JTI has made significant duty and tax payments to the UK Exchequer. For example, Tobacco Product Duty payments made by JTI in the 2011 calendar year amounted to over £3.6 billion. JTI's total payments to the UK Exchequer in the past 4 years amounted to over £17 billion.
- 5.11 Plain packaging which would have the unintended consequence of increasing the availability of lower-priced illicit products will shift employment opportunities away from the legitimate industry's skilled workforce, including those within JTI's UK sites. JTI employs over 1,800 people in the UK. It operates a manufacturing site at Lisnafillan, Northern Ireland, employing over 900 people, as well as sites in Weybridge, Crewe and Manchester. As noted above, it will also add to the losses to the UK Exchequer caused by the illicit trade losses already put at up to £3.1 billion per year.
- 5.12 The UK is meant to be 'open for business'. According to BIS, "[g]rowth is the Government's top priority and every part of Government is focused on it". But plain packaging disproves that claim. Not only because of the negative effects on retailers and the supply chain, and the additional negative effects highlighted in this section, but also because plain packaging demonstrates a fundamental disregard for the protection of intellectual property, and the investments JTI and others have made to establish and develop that property (discussed further below). This is echoed by the independent Hargreaves Report to the UK Government, which notes that "trade marks are associated with growth" and that the "association of brands and business growth is particularly clear in the branded fast moving consumer goods sector". 165

5.13 A group of major manufacturers that supply tobacco packaging material and operate both within the UK and internationally warned: "The adoption of plain packaging would send a message to our investors and to the other companies and organisations that rely or place value on brands and trademarks that the Government cannot be relied upon to protect intellectual property rights and the UK is a relatively hostile environment for doing business". ¹⁶⁶

EROSION OF BRAND EQUITY AND A DISPROPORTIONATE IMPACT ON PREMIUM BRAND OWNERS

- 5.14 Central to JTI's business are its brands, including premium brands in the UK, like Benson & Hedges Gold and Silk Cut. JTI has invested very substantially in them, as reflected by the brand awareness and strong positive associations that the brands have engendered amongst adult smokers.
- 5.15 Plain packaging eradicates branding and will erode brand equity, most notably in leading, premium brands. Premium brands will therefore be disproportionately affected as they have most to lose. Plain packaging will impact JTI to an even greater extent than other tobacco manufacturers whose market share consists largely of subpremium or value brands, or even own-label brands.
- 5.16 The discriminatory effect of plain packaging for JTI would be exacerbated if, as JTI believes will happen, plain packaging were to lead to further downtrading in consumer purchasing. JTI's approach to this issue is informed by the work undertaken by Dr Lilico regarding the impact of plain packaging on competition and the tobacco market. Dr Lilico anticipates, amongst other things, large-scale downtrading into lower quality products, including a reduction in market share for the premium segment and an increase in the value for money segment. Further, average prices for tobacco products as a whole fall in a plain packaging scenario. These points are demonstrated through the results of a simulation model, where his conclusion is borne out robustly and reproduced in all cross-checks (see paragraphs 5.24 to 5.37 below).
- 5.17 Any price drops caused by plain packaging are at odds with the DH's aim of reducing smoking initiation by minors, as it has stated that lower prices generally mean increased availability and greater access for minors to tobacco products. The RPC expressed the same concern: "The IA acknowledges that as a result of this proposal, there is the possibility that tobacco companies will decide to compete on other grounds, if they can no longer compete on branding" and proposed that "The IA should discuss clearly the risks of how tobacco manufacturers are likely to respond to the [plain packaging] proposal in terms of achieving the policy objectives of reducing smoking". ¹⁶⁹

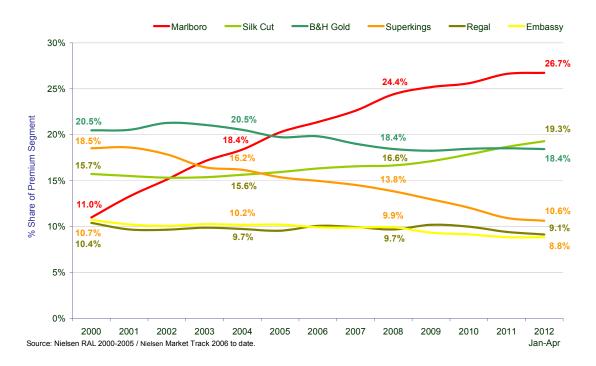
SERIOUS AND UNNECESSARY DAMAGE TO THE LEGITIMATE ECONOMIC INTERESTS OF TOBACCO MANUFACTURERS AND COMPETITION IN THE UK TOBACCO SECTOR

The UK tobacco market: inter- and intra- brand competition

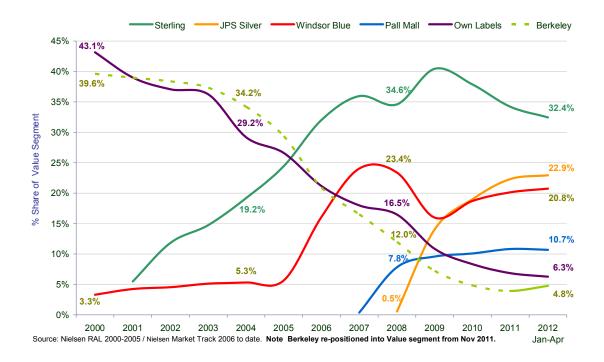
5.18 In the UK's system of undistorted competition, businesses must be in a position to communicate to their customers. The UK tobacco market is highly

competitive. The graphs below demonstrate that it is a mature and declining market in which tobacco manufacturers compete and innovate in order to increase market share amongst existing adult smokers. It is also clear from these graphs that the market share of UK brands fluctuates significantly, illustrating that there is genuine inter-brand competition, particularly when a new brand or product is introduced to the market.

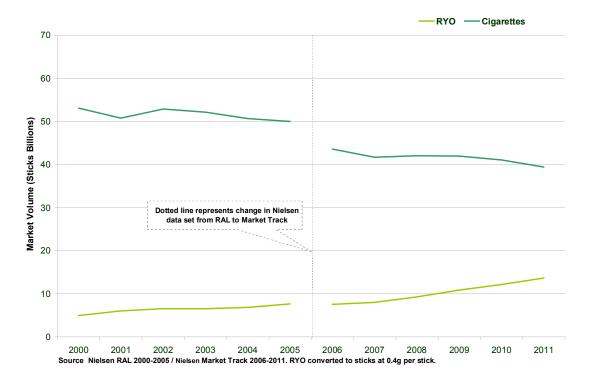
UK Cigarette Share of Premium Price Segment (%)



UK Cigarette Share of Value Price Segment %



UK Ready-Made-Cigarette (RMC) and RYO Volume



5.19 JTI invests and innovates in its packaging design and quality in order to compete with other products available to existing adult smokers. JTI and other

companies, both within the tobacco sector and also in the context of other FMCGs, use product packaging in a myriad of ways, and this scope for creativity motivates efforts to differentiate the product from others. Packaging comes in many different shapes, sizes, colours, designs and materials. One specific, functional example is the way a cigarette pack opens: as well as packs using a flip-top lid, consumers can choose soft packs, 'push and slide' packs and front opening packs (as in a classic cigarette case). In relation to RYO pouches, choices exist between pouches alone or pouches provided with papers and filters.

- 5.20 Consumers are entitled to expect a product to be of a quality consistent with previous experience and to hold the trade mark proprietor liable for failure to perform. In that context, trade marks guarantee the identity of origin of the marked goods or services to consumers by enabling them, without any possibility of confusion, to distinguish the goods or services from others which have another origin. If packaging is no longer distinctive:
- (a) competition is distorted because consumers are less able to identify their choice of product or select alternative products; and
- (b) the responsibility of the trade mark proprietor to the consumer is potentially jeopardised as consumers are less likely to be sure of the origin and quality of the goods they buy.

Impacts on legitimate economic interests and competition

- 5.21 JTI's assessment of impacts on competition is informed by Dr Lilico's expert analysis. Dr Lilico gave his expert opinion in his 2008 report, and subsequently reproduces and expands his theory in the light of a simulation model.
- 5.22 Dr Lilico's expert opinion is that "a plain packs requirement should be expected to have very significant negative competition effects" in the UK.¹⁷¹ It is highly likely that plain packaging will result in:
- (a) a significant reduction in the typical 'brand switching' activity that JTI would normally expect to see carried out by existing adult smokers in the UK market, as consumers' navigation between brands is frustrated. Consumers are left to request and purchase those brands of tobacco products familiar to them. As Dr Lilico notes, plain packaging "reduc[es] the ability of consumers to engage in informed switching"; 172
- (b) a significant reduction in consumer choice in legitimate tobacco products as JTI and other manufacturers of legitimate tobacco products are hampered in their ability to successfully launch new brands into the market. Plain packaging would "raise barriers to entry for new brands" and result in "the

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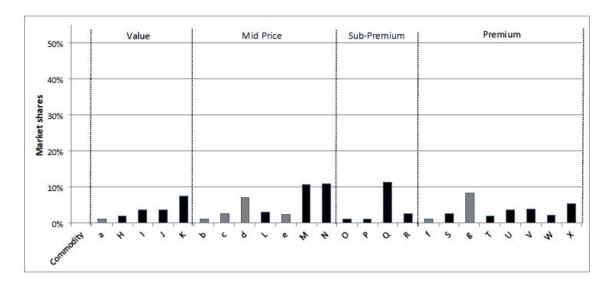
Professor Gervais' Report, paragraph 44: "Modern trade mark theory has recognized that trade marks protect not only the owners of marks but also consumers, especially by reducing search costs. Trade marks allow consumers to identify lawful products that they wish to purchase. They can normally expect a certain quality that they associate with a given trade mark. By making all packages more or less similar, this function, which is tied to the essential function of a trade mark to guarantee the origin of products bearing the mark, is impaired".

- reduced capacity for new products to enter the market challenging existing products, other than at the lowest quality/price level";¹⁷³
- (c) a total elimination of pack innovations and many potential innovations in tobacco products would be rendered all but infeasible. In light of this expert evidence, the assertion in the IA that "[a]nother effect of standardised packaging could be an acceleration in product innovation... and process innovation... and process innovation...
- (d) changes to the market structure, prices and market concentration (see below) to an extent that Dr Lilico states "would normally be considered of interest and concern to policymakers, as measured on their own standard criteria. Indeed, a key reason competition impacts are assessed in regulatory analysis is to avoid introducing regulations that so vest market power and damage competition." ¹⁷⁶
- 5.23 As identified at Sections 4 and 5 of Dr Lilico's 2008 Report, the operation of competitive markets provides stimulus for innovation and the provision of products with distinct characteristics, leading to a wider choice and greater efficiency. In the absence of the ability to distinguish products by virtue of packaging, manufacturers may be reluctant to invest in research and development (R&D) and new products.

Formal simulation model of market impacts

- 5.24 Dr Lilico has modelled the competition effects formally in a simulation model deploying standard economic theories and mathematical modelling techniques applied to vertical product differentiation, signalling and adverse selection. The simulation model, based on UK data for RYO and RMC products, calibrates so as to reflect well the recent UK tobacco market (although brands are anonymised as the model does not purport to make predictions about individual brands) and produces results that are qualitatively robust to multiple cross-checks. The effects of plain packaging are modelled as a reduction in brand characteristic awareness. As it is not possible, on the basis of the Consultation, to quantify mathematically the degree of reduction in brand awareness, Dr Lilico modelled various scenarios. Dr Lilico states, "our judgement... is that one should expect enough brand degradation, from a plain packs requirement, to produce scenarios of these sorts". 178
- 5.25 For each of the scenarios, Dr Lilico has explored (a) the impact on brand survival and market shares (i.e., the market structure), (b) the impact on prices, and (c) the impact on competition, as evidenced by impacts on concentration and on profits above marginal costs (as those costs are calibrated by the model).
- 5.26 As to the impact on **brand survival and market shares**, Dr Lilico used as a basis the status quo of the UK market, demonstrated on the graph below:

Status Quo Scenario



5.27 The simulation model produces the following results, assuming that plain packaging degrades brand awareness by 10%, 25% and 50% (degradation which Dr Lilico describes as "modest").

10% brand degradation scenario



25% brand degradation scenario



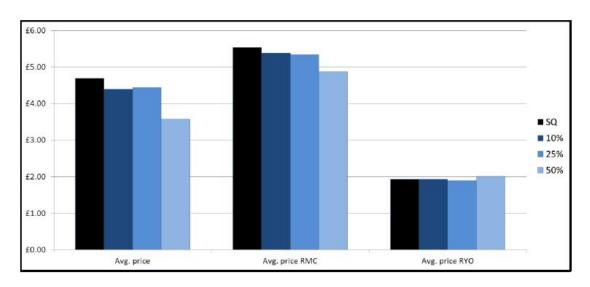
50% brand degradation scenario



- 5.28 These graphs clearly demonstrate damages to market competition:
- (a) the pattern of focus is upon a small number of brands per segment (other than in the value range); and
- (b) there is large-scale downtrading into lower quality/price products. Indeed, at 25% and 50% brand degradation, the premium segment has been eliminated entirely.
- 5.29 Dr Lilico states that these "key conclusions of our model are robust and reproduced in all our cross-checks". 179

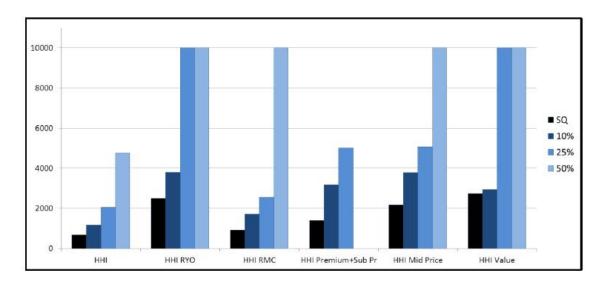
5.30 As to the impact on **prices**, Dr Lilico's model demonstrates that average prices for tobacco products as a whole fall when plain packaging results in even modest degrees of brand degradation. He finds that "the prices for RMC products as a whole fall (as RMC products tend to include higher quality brands that would be driven from the market) whilst those for RYO products are broadly stable." His findings are set out in the figure below.

Average prices by segment and brand power degradation (overall averages)



- 5.31 The effect of plain packaging on the prices on individual brands is more complex. Dr Lilico concludes that, on the basis of his model, "for modest degrees of brand degradation, effects on prices of individual brands vary prices for some products rise (as market power increases) whilst those of others decrease (as consumer uncertainty reduces the willingness to pay for quality)". ¹⁸¹
- 5.32 As to the impact on **concentration**, Dr Lilico's model addresses two characteristics of market concentration. First, he addresses the impact of plain packaging on the degree of competition in a market (by calculating the impact on the Herfindahl-Hirschman index (*HHI*) value in various scenarios being the standard market concentration indicator employed by competition authorities in merger cases). Second, he considers the impact on profit above marginal costs.
- 5.33 First, the model demonstrates a rise in the HHI of brands as competition declines. Dr Lilico states: "the net effect of the changes in market structure discussed above is an increase in market concentration (even for modest degrees of brand characteristic awareness degradation), as measured by the HHI." This increase in concentration occurs materially across the board. HHI increases of 250 points raise significant competition concerns under EU and US merger rules; the model shows increases of 510, 1380 and 4090 points for the three scenarios (see figure below).

HHI by segment and 10% to 50% brand power degradation



- 5.34 Dr Lilico summarises that "the increases in concentration are of a scale that would normally be considered of interest and concern to policymakers, as measured on their own standard criteria. Indeed, a key reason competition impacts are assessed in regulatory analysis is to avoid introducing regulations that so vest market power and damage competition." ¹⁸³
- 5.35 These results show how clearly and fundamentally plain packaging impacts competition; the DH has not conducted such relevant analysis, and JTI believes that Dr Lilico's findings should give rise to a radical re-appraisal of the proposal. Government regulation should not damage competition in this way.
- 5.36 Second, Dr Lilico's model suggests that as a result of the changes in market structure, discussed above, there is likely to be an increase in market power. Many players and products are driven out of the market altogether. His model suggests that this increase in market concentration is also associated with a rise in above-marginal cost profits for those few players and products that survive, while simultaneously reducing profits for all other firms. Dr Lilico emphasises that this is not a prediction that the tobacco industry would make increased total profits. Given the large-scale downtrading, and ultimately few remaining brands, he notes that "if the premium market segment loses market share then aggregate normal profits for the industry would fall... thus we might have two partially-offsetting factors: a rise in profits above marginal costs but a fall in normal profits." His results reinforce the HHI result, suggesting increased concentration is indeed associated with increased market power.
- 5.37 In conclusion, both economic theory and the simulation exercise demonstrate the severe impacts of plain packaging on competition, including:
- (a) Market dynamics will be impaired: as brand awareness degrades, competition initially becomes fixated on one or two brands for most price segments (damaging within-price-segment competition) and eventually there is large-scale downtrading into lower quality products. This would be

particularly detrimental to innovative manufacturers and manufacturers who sell a wide variety of products.

- (b) **Increase in market concentration**: many players and products would be driven out of the market. A key reason competition impacts are assessed in regulatory analysis is to avoid introducing regulations that so vest market power and damage competition.
- (c) **Price effects/potential commoditisation**: plain packaging would lead to downtrading and tend towards commoditisation at the value end of the market for extreme levels of brand degradation. For just modest degrees of brand degradation, average prices of tobacco products (and cigarettes in particular) fall.

The DH has previously indicated that if a decrease in price were to follow the introduction of plain packaging, increases in tax on tobacco could counter the effect. High tobacco taxation rates and/or tax rates largely in excess of those practiced in neighbouring countries have already resulted in UK consumers increasingly purchasing lower-priced tobacco products rather than premium brands, and have encouraged the illicit trade in tobacco products. As noted at paragraph 5.31 of Dr Lilico's 2012 Report, the risk of counterfeit and contraband increasing might well limit the scope for tax rises to offset these price falls.

- (d) **Lowering of quality standards**: a downward shift in product prices could lead to a reduction in the quality of tobacco products as margins are impacted, as well as reduced incentive to innovate and introduce products containing particularly high quality, or specialised, tobacco. Further, where price becomes increasingly significant as the key product differentiator, barriers to entry are created other than at the cheapest price point for the product.
- (e) A reduction in consumer choice and a barrier to manufacturers entering the market with new brands (other than those reliant on lower prices as a differentiator), as discussed above.

6. DEPRIVATION OF PROPERTY AND/OR THE IMPAIRMENT OF FUNDAMENTAL LEGAL RIGHTS

THE FUNDAMENTAL ROLE OF INTELLECTUAL PROPERTY RIGHTS IN TOBACCO PACKAGING

- 6.1 JTI owns a broad range of sophisticated IPRs in relation to its tobacco products (including registered UK and Community trade marks, xxvi unregistered trade marks, community design rights and other rights).
- 6.2 JTI's portfolio of trade marks at the UK and the EU level includes over 100 applications and registrations in respect of tobacco products sold in the UK, some of which have been registered for over a century. In this context, trade marks may take a variety of forms including word marks (for example, for the name of a brand) and non-word marks (such as device or figurative marks, including logos, designs, stylised characters, combinations of logos and stylised characters, colour marks and the shape of goods or their packaging). xxviii
- 6.3 By way of example, the following illustrates the trade mark registrations that relate to certain Benson & Hedges and Camel variants, each of which is a JTI product.



The law relating to UK registered trade marks is governed by the Trade Marks Act 1994 Act (the 1994 Act) which is intended to give effect to Directive of the European Parliament and of the Council of 22 October 2008 to approximate the laws of the EU Member States relating to trade marks (codified version) (2008/95/EC) (the Trade Marks Directive). The law in relation to Community trade marks is governed by Council Regulation of 26 February 2009 on the Community trade mark (codified version) (207/2009/EC) (the CTMR).

xxvi Unregistered marks are protected in the UK by an action for passing off.

The law relating to Community design rights is governed by the Council Regulation of 12 December 2001 on Community designs (6/2002/EC). Article 19 of that Regulation provides that a "registered Community design shall confer on its holder the exclusive right to use it".

xxviii The broad range of types of trade marks, that are capable of protection by registration, is expressly recognised by UK and EU legislation: see Section 1(1) of the 1994 Act, Article 2 of the Trade Marks Directive and Article 4 of the CTMR.

- 6.4 Extensive efforts are taken to protect these rights by way of a rolling programme of trade mark applications, registrations, oppositions, renewals and enforcement actions. Those enforcement efforts include registered trade mark infringement actions and actions to protect its unregistered proprietary rights (e.g., by way of a passing off claim) by JTI, in addition to actions taken by regulatory enforcement agencies.
- 6.5 The existence and uniformity of protection of IPRs have been recognised as of paramount importance to the functioning of the EU internal market¹⁸⁶ and as necessary incentives for investment in R&D and innovation. The development of brand equity and goodwill is fundamental to market economies, consumer choice, innovation and product development. It flows, as economic value, through all levels of the supply chain.
- 6.6 In addition to the status attributed to them by UK and EU legislation, xxix and international treaties, 187 the economic, commercial and consumer protection significance of IPRs have been consistently reaffirmed by EU institutions and respected independent reports. For example:
- the European Commission stated "[i]n today's knowledge-based society intellectual property rights (IPR) are vital business assets, encouraging innovation and creativity by ensuring a fair return on investment. IPR play an increasingly important role, fostering economic growth by protecting and enabling inventors, designers and artists to benefit from the commercial value of their creations. This results in an essential cycle of business development, knowledge and further innovation. Moreover, trade marks in particular can have a beneficial effect on consumers, in many cases signifying quality and a reassurance that the products and services they buy are legitimate, safe and reliable" (emphasis added); 188
- (b) the Council of the EU emphasises "the importance of protecting intellectual property rights, which are fundamental to promoting culture and diversity, and for drawing full benefit from the research, innovation and creative activity of European undertakings, especially small and medium sized enterprises, in order to support growth and jobs in the European Union and make Europe more competitive in the world". 189

THE FUNDAMENTAL RIGHT TO PROPERTY

- 6.7 A plain packaging measure, if it could be adopted at all, would deprive JTI of its most valuable assets. JTI's brands are worth billions of pounds. Deprivation of property is presumed to be disproportionate and hence unlawful unless JTI is compensated at the full value of its property. 190
- 6.8 JTI has invested very substantially in its IPRs, brands and products, and this is reflected in the strong brand equity of JTI's brands in the UK. It is difficult to see

xxix By way of illustration, see Recitals (3) to (13) of Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights. See also paragraphs 6.7 to 6.20 below.

how a proposal of this nature could be advanced without a corresponding proposal to compensate JTI and other brand owners for the value of their property.

- 6.9 The fundamental right to property is recognised in Article 1 of Protocol 1 of the European Convention on Human Rights (*ECHR*), and is one of the rights scheduled to the Human Rights Act 1998. The ECHR guarantees that every person is "entitled to the peaceful enjoyment of his possessions" and that property rights are "practical and effective". 191 Article 6(3) of the Treaty on European Union states that the rights guaranteed by the ECHR, including the right to property, "shall constitute general principles of the Union's law". 192 The right to property is also enshrined in the EU Charter of Fundamental Rights, which states that "everyone has the right to own, use, dispose of and bequeath his or her lawfully acquired possessions". 193 The Charter is now binding on the UK and has "the same legal value as the Treaty on European Union and the Treaty on the Functioning of the European Union". 194
- 6.10 JTI's IPRs, including its Community and UK registered trade marks and the goodwill associated with its trade marks, are property rights¹⁹⁵ to which this protection extends.¹⁹⁶ Effective and adequate protection of such rights is enshrined in EU and international law. UK courts are required to apply national and EU legislation in the light of the wording and purposes of international law.¹⁹⁷
- 6.11 Reflecting this fact, in the UK, trade marks can be protected by registration at the national level (in the UK, under the 1994 Act, which implements the Trade Marks Directive) and/or at the EU level (CTMR¹⁹⁸). Trade marks registered at the EU level (*CTMs*) are unitary in character and protected for the whole of the territory of the EU, including the UK. JTI is the proprietor of both UK trade mark registrations and CTMs.
- 6.12 Use by JTI of its trade marks is recognised by UK, ¹⁹⁹ EU^{xxxii} and international ²⁰⁰ law as being a central and essential element of trade mark ownership. In addition, the scope of the rights reserved exclusively to the proprietor of a registered trade mark are specified under UK²⁰¹ and EU²⁰² law and include affixing the protected mark to the goods or packaging and offering goods for sale under the protected mark.
- 6.13 The specific subject matter of a trade mark includes not only the essential function, which is to guarantee to consumers the origin of the goods or services

In addition, a protected international trade mark (UK), which is applied for under the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks, is also protected in the UK as if it were a trade mark registered under the 1994 Act, by virtue of sections 53 and 54 of the 1994 Act and the Trade Marks (International Registration) Order 2008 (SI 2008/2206).

The provisions of the Trade Marks Directive mirror those of the CTMR for the purpose of ensuring that the protection conferred by registration is, in substance, the same under both the national and CTM regimes. The rights of the registered trade mark proprietor are defined in Sections 9 to 12 of the 1994 Act; Articles 5 to 7 of the Trade Marks Directive; and Articles 9, 12 and 13 of the CTMR.

Recital (9) of the Trade Marks Directive makes clear that "[i]n order to reduce the total number of trade marks registered... in the Community... it is essential to require that registered trade marks must actually be used or, if not used, be subject to revocation". Recital (10) of the CTMR states that "[t]here is no justification for protecting Community trade marks or, as against them, any trade mark which has been registered before them, except where the trade marks are actually used". See Articles 10 to 12 of the Trade Marks Directive and Articles 15, 42(2), 51 and 99(3) of the CTMR under which rights may lapse or become unenforceable.

concerned,²⁰³ but also associated functions including the function of guaranteeing and communicating to consumers the product's quality, integrity and reliability (as well as other characteristics), and the goodwill or investment function.²⁰⁴ As a proprietor of such trade marks, JTI has a legitimate interest, related to the specific subject matter of the trade mark right, which it is entitled to protect.²⁰⁵

- 6.14 Registration of a trade mark confers the exclusive right on the proprietor to prevent third parties not having his consent from doing certain specified acts.²⁰⁶ This allows the proprietor to prevent acts by a third party that will "affect or be liable to affect the functions of the trade mark".²⁰⁷ The protection conferred by registration of a trade mark is broader for marks that have a distinctive character as a result of the use made of them,²⁰⁸ and for marks with a "reputation". **xxxiii* Registration also confers the legal right to object to the way in which the goods are subsequently presented for sale and sold, including the right to object to 'de-branding' of the packaging of the goods.²⁰⁹
- 6.15 As soon as it came into effect, a plain packaging measure would be a complete prohibition on the fundamental, consumer-facing, use of a substantial part of JTI's trade mark portfolio in the UK, and would also have significant adverse effects on JTI's other IPRs. Such a measure would involve the suppression of the origin, quality, information, communication and goodwill functions of registered trade marks to a degree that undermines the commercial rationale for trade marks as recognised by the European Court of Justice, and as protected under UK and EU trade mark legislation.
- 6.16 A plain packaging measure would leave JTI unable to exploit its IPRs commercially, which would render them, for all practical purposes, valueless in the UK. At the very least, mandating plain packaging would prevent JTI from making the most fundamental use of its trade marks (i.e., on the consumer-facing packaging of the product and the product itself) thereby depriving JTI of the benefit and economic

Case C-487/07 L'Oréal SA v. Bellure NV [2009] ECR I-5185, paragraphs 34 and 59, where the Court of Justice held, inter alia, (1) that the protection conferred by registration of a trade mark is broader under Article 5(1)(a) of the Trade Marks Directive/Article 9(1)(b) of the CTMR than it is under Article 5(1)(b) of the Trade Marks Directive/Article 9(1)(b) of the CTMR (see also Joined Cases C-236/08 to C-238/08 Google France v Louis Vuitton [2010] ECR I-0000, paragraph 78); and (2) that the protection conferred by registration of a trade mark is broader under Article 5(2) of the Trade Marks Directive/Article 9(1)(c) of the CTMR than it is under Article 5(1) of the Trade Marks Directive/Article 9(1)(a) of the CTMR. This principle is also recognised in Article 6bis of the Paris Convention and Articles 16.2 and 16.3 of TRIPS in relation to well-known marks. As paragraph 25 of Professor Gervais' Report states, "preventing or substantially restricting the use of a mark may prevent its development and the acquisition of well-known mark (or mark with a reputation) status and, consequently, the broader scope of protection associated with such status".

The enforcement of the rights conferred by the registration of a trade mark "cannot continue to operate if the mark loses its commercial raison d'être, which is to create an outlet for the goods that bear the sign of which it is composed as distinct from the goods of other undertakings": see Case C-495/07 Silberquelle GmbH v. Maselli Strickmode GmbH [2009] ECR I-137, paragraph 18. See also Case C-40/01 Ansul BV v. Ajax Brandbeveiliging BV [2003] ECR I-2438, paragraph 37 and Case C-442/07 Verein Radetzky-Orden v. Bundesvereinigung Kameradschaft 'Feldmarschall Radetsky' [2008] ECR I-9223, paragraph 14. Further, the Court of Justice has recognised the important significance of trade marks both at the point of sale (Case C-361/04 Claude Ruiz-Picasso v. OHIM [2006] ECR I-643, paragraphs 39 and 40; and Case C-24/05 August Storck KG v. OHIM [2006] ECR I-5677, paragraphs 71 and 72) and post-sale (Case C-361/04 Claude Ruiz-Picasso v. OHIM [2006] ECR I-643, paragraph 46; and Case C-245/02 Anheuser-Busch Inc v. Budějovický Budvar [2004] ECR I-10989, paragraph 60. See also Case C-206/01 Arsenal Football Club plc v. Reed [2002] ECR I-10273, paragraphs 56 and 57).

value of the specific subject matter of these marks. Forcing brand names to be written in a standard typeface, colour and size is also a fundamental and entirely unjustified restriction on the normal and fair use of JTI's word trade marks.

- 6.17 Mandating plain packaging would destroy the substance of the property to such a degree that it would constitute a deprivation. This equates to the total extinction of ownership and protection, and goes beyond "impairing the very substance of the rights guaranteed". ²¹⁰
- 6.18 A plain packaging requirement would have at least the following IPR-related impacts:
- (a) it would prohibit the fundamental consumer-facing use of JTI's trade marks, as exclusively reserved to JTI, and as recognised by UK and EU case law;²¹¹
- (b) the protected functions of JTI's registered UK trade marks and CTMs, in particular the guarantee of origin function, xxxvi the guarantee of quality function, xxxvi the communication function and the goodwill or investment function, would be suppressed;
- (c) as JTI would be prevented from using its trade marks on the consumer-facing packaging of its products, its ability to take action:
 - (i) to prevent acts by a third party that affect or are liable to affect the functions of its UK trade marks or CTMs would be impaired;²¹²
 - (ii) to protect its UK trade marks, and certain CTMs, with a reputation would be diminished and ultimately extinguished. This right to extended protection for JTI's registered trade marks with a reputation²¹³ would ultimately be lost; and
 - (iii) to oppose trade mark applications and apply to invalidate trade mark registrations at either a national or EU level would likewise be affected;²¹⁴
- (d) JTI would lose its proprietary rights in respect of unregistered trade marks, thereby preventing it from being able to sue for passing off in the UK and from relying on such rights in the context of opposition or invalidity proceedings either at the national or the EU level;²¹⁵
- (e) depending on the formulation of the measure, JTI's UK registered trade marks (and in certain circumstances its CTMs) may be vulnerable to revocation, ²¹⁶ JTI's current UK national trade mark registrations or CTMs

xxxv The IA acknowledges, at paragraph 94, that "[t]he effect of standardised tobacco packaging could be further to erode the ability of tobacco companies to distinguish their brands from one another".

xxxvi The IA acknowledges that plain packaging would have an adverse effect on the quality function of trade marks. It states, at paragraphs 21 and 29, that "tobacco in standardised packs can be perceived to be of poorer quality" and "[t]he evidence review found that smokers' perceptions of the quality of tobacco can be influenced by branding".

could be declared invalid, and its future trade mark applications may be refused or, if granted, subsequently invalidated;²¹⁷

- (f) to the extent that JTI was deprived of its trade mark registrations:
 - (i) JTI would be deprived of its ability to prevent third parties not having JTI's consent from doing certain specified acts;²¹⁸
 - (ii) JTI would be deprived of its ability to oppose trade mark applications and apply to invalidate trade mark registrations at either a national or EU level;²¹⁹ and
 - (iii) UK regulatory authorities would be deprived of their ability to take action to tackle illicit trade of tobacco products whether by criminal prosecutions or under Regulation (EC) No. 1383/2003; xxxvii and
- (g) by significantly impairing the protection afforded to tobacco-related trade marks in the UK, a plain packaging requirement would be contrary to the expressed purpose of the Trade Marks Directive and the CTMR to ensure uniformity of trade mark protection throughout the EU, for the proper functioning of the internal market.²²⁰
- 6.19 The fact that a UK plain packaging measure would prohibit the use of CTMs in the UK means that such a measure would be incompatible with the unitary character of the CTM, as set out in Article 1(2) of the CTMR. That Article provides that "[a] Community trade mark shall have a unitary character. It shall have equal effect throughout the Community: it shall not be registered, transferred or surrendered or be the subject of a decision revoking the rights of the proprietor or declaring it invalid, nor shall its use be prohibited, save in respect of the whole Community. This principle shall apply unless otherwise provided in this Regulation". The DH has failed to explain the basis on which it believes it has competency to introduce a plain packaging requirement in light of the CTMR, or how plain packaging would be compatible with that EU Regulation.
- 6.20 The destruction of the substance of JTI's IPRs would have a direct impact on the value of its assets. According to international standard ISO 10668:2010²²¹ on brand valuation, the appraisal of a brand's value "shall include an assessment of the legal protection afforded to the brand, identifying... the legal parameters influencing negatively or positively the value of the brand". This standard states that those legal parameters include "distinctiveness... scope of use... extent of use... notoriety/extent to which [the] brand is well-known... [and] ability of the owner to enforce legal

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Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property. HMRC can only take action where goods suspected of infringing IPR are in the process of being introduced into or exported from the EU customs territory. Where, to a large extent, trade mark protection is not available in relation to tobacco products in the UK, HMRC will not be in a position to prevent importation of counterfeit tobacco products (i.e., counterfeit tobacco products in the packaging legally used throughout the rest of the EU). The UK would become the 'weak link' in EU wide efforts to tackle illicit trade in this way as, once such products have entered into free circulation within the EU, no other Member State customs authority may detain such goods under this Regulation.

rights". Plain packaging adversely affects each of those parameters, thereby significantly reducing the value of the relevant trade marks.

THE UK'S INTERNATIONAL LEGAL OBLIGATIONS

- 6.21 In addition to the points outlined above, the burden would be on the UK, as a WTO member, to demonstrate that a plain packaging measure is consistent with its obligations under the World Trade Organization's Agreement on Trade-related Aspects of Intellectual Property Rights (*TRIPS*) and other international laws on IPRs, including the Paris Convention for the Protection of Industrial Property (the *Paris Convention*), and the World Trade Organization's Agreement on Technical Barriers to Trade (*TBT*). 222
- 6.22 JTI believes that the adoption of a plain packaging measure would be in violation of these international obligations, and could give rise to disputes under the WTO Dispute Settlement Understanding. JTI's view is based on the opinion of Professor Gervais on the interpretation of TRIPS and the Paris Convention (Annex 7 of this Response).
- 6.23 In particular, Article 20 of TRIPS requires that:
 - "The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trade mark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings".
- 6.24 Plain packaging would be a special requirement encumbering the ability of JTI (and other manufacturers) to distinguish its goods through its trade marks from those of other entities. It would prohibit the use of non-word marks on packaging and would also require JTI to use its word marks "in a special form". IP Australia, which administers Australia's patents, designs, trade marks and other IP systems and advised the Australian government on IPR issues during the preparation of the Australian plain packaging legislation, has stated that "this Article was drafted with the intention of restricting mechanisms like plain packaging". ²²³
- 6.25 JTI acknowledges that WTO members may, in certain limited circumstances, take advantage of flexibilities within TRIPS to address public health concerns. Article 8.1 of TRIPS allows for members to "adopt measures necessary to protect public health". However, this Article is not an exception to Article 20, but rather a statement of principle. Indeed the final part of this Article stipulates that such measures have to be consistent with the rest of the provisions of TRIPS. There are, therefore, threshold issues as to whether Article 8 can be used at all to override a breach of Article 20.
- 6.26 JTI believes that the UK would be unable to demonstrate that plain packaging is either 'justified' (Article 20) or "necessary" (Article 8) to achieve a legitimate public policy objective. Having regard to, first, the lack of reliable evidence that the

Objectives would be achieved by plain packaging xxxviii and, second, to the availability of less trade-restrictive alternative measures, 225 JTI considers that plain packaging would breach TRIPS.

6.27 Other relevant international IPR treaty provisions include Article 7 of the Paris Convention and Article 15.4 of TRIPS. Article 7 states that:

"The nature of the goods to which a trademark is to be applied shall in no case form an obstacle to the registration of the mark".

- 6.28 Article 15.4 of TRIPS is in essentially the same terms. Plain packaging deprives JTI of the ability to use non-word trade marks for tobacco products. In the context of UK and EU trade mark law, ²²⁶ plain packaging would restrict trade mark registrations solely by reference to the "nature of the goods", and therefore would also violate these Articles.
- 6.29 A plain packaging measure would also breach TBT requirements. JTI believes that mandatory plain packaging would be contrary to Article 2.2 TBT, which provides that:

"Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create".

- 6.30 For the reasons identified above, there is no genuine relationship of ends and means between the Objectives pursued and plain packaging. There is no prevailing scientific consensus (or sufficient reliable evidence) that plain packaging would bring about a material contribution to changing smoking behaviour. In any event, there are reasonably available alternative measures that will achieve the UK's goals at its chosen level of protection.
- 6.31 JTI is not alone in its view that plain packaging breaches TRIPS and TBT. A significant number of countries that are members of the WTO have repeatedly argued against Australia's plain packaging legislation, claiming that it infringes TRIPS, the Paris Convention and/or TBT requirements. In particular, it has been argued that the Australian plain packaging legislation:
- (a) would have a detrimental impact on trade mark owners;²²⁷
- (b) could create unnecessary barriers to trade, since the measure is more trade restrictive than necessary to achieve Australia's public health objective (under Article 2.2 TBT);²²⁸ and
- (c) has not been accompanied by sufficient scientific evidence linking plain packaging to a reduction in tobacco consumption, especially among minors. 229

xxxviii As set out in this Response, there is, without doubt, no prevailing scientific consensus (or sufficient evidence) that plain packaging would bring about a material contribution to the Objectives (see *Brazil-Tyres*, Appellate Body Report, WT/DS332/AB/R, 3 December 2007, paragraph 151).

In other words, the members of the WTO questioned the efficacy of the measure to achieve the stated objective.

- 6.32 Reinforcing the seriousness of these concerns, Ukraine (on 13 March 2012)²³⁰ and Honduras (on 4 April 2012)²³¹ respectively issued Requests for Consultations (*Requests*), the first step towards a formal WTO dispute. These Requests refer to the inconsistency of Australia's plain packaging measure with TRIPS, Paris Convention and TBT requirements (including those described above).
- 6.33 In addition to Professor Gervais' opinion, the international, EU and UK law concerns regarding plain packaging have been expressly recognised by both governments and expert bodies:
- (a) a European trade mark organisation, MARQUES, together with its sister organisations (Association des Praticiens du Droit des Marques et des Modèles (APRAM), the Benelux Association of trade mark and design law (BMM), the European Communities Trade Mark Association (ECTA), the German Association for the Protection of Intellectual Property (GRUR) and the Union of European Practitioners in Intellectual Property (UNION)), have issued a joint press release in the context of the Consultation stating that:
 - (i) "trade marks and trade dress are relied upon by consumers as signposts of genuine goods and services. This is true for both word marks and figurative marks (graphical devices), and for signs resulting from the combination of the two, as well as so called "non-traditional" trade marks such as packaging shapes and colours per se. Trade marks also indicate the source of goods and services to assure consumers on the quality of the products that they purchase or that they would consider purchasing. This fundamental function cannot be fulfilled if trade marks are not noticeable, or unavailable, to consumers when selecting a product. The inability to recognize a brand or trade mark on a product would lead to consumer confusion, and therefore diminish the goodwill acquired in that brand through considerable investment and effort over a significant period of time. In fact the inability to call for or recognize a brand also takes away a consumer's freedom of choice"; and
 - (ii) "The IP business and professional communities have very strong concerns that any legislation that precluded whether fully or in part brand owners from the ability of making legitimate use of their trade marks, would amount to an indirect legislative expropriation of private intellectual property and, as a consequence, lead to the extinction of their property rights. Any such legislation would adversely affect the markets, with harmful impacts on the economy as a whole as would be derived from escalating counterfeiting and piracy throughout the EU and worldwide. Where there is a need to achieve important public objectives, any developing legislation and/or policy options should not deviate from maintaining an appropriate balance with legitimate intellectual property and other proprietary rights"; ²³²

- (b) Peter Lawrence, the former head of the UK Patent Office (now known as the UK Intellectual Property Office) and former Vice-President of the Office for Harmonisation in the Internal Market, has stated that "[t]he UK has fought hard at international level to ensure that all countries respect trade mark rights, and for the UK to take action to deprive brand owners of the right to use their marks would be an unfortunate precedent to say the least. There may be circumstances in which the public interest would justify such a move, but I do not think that the case has been made here for such a radical step. Trade marks underpin modern economies by helping consumers make their choices and bring rewards to firms that successfully meet their desires. When governments seek to intervene in this way, they risk undermining this fundamental aspect of how markets operate". 233
- (c) IP Australia advised²³⁴ the Australian Government that "plain packaging may not be consistent with Australia's intellectual property treaty obligations". IP Australia acknowledged that "requiring plain packaging would be regarded as encumbering [within Article 20 of TRIPS] the ability of an entity to distinguish its goods through its trade marks from those of other entities. IP Australia's understanding is that this Article [20] was drafted with the intention of restricting mechanisms like plain packaging'. Further, on Article 8(1) of TRIPS, IP Australia notes that "it seems unlikely that this Article could be used to avoid Article 20";²³⁵
- (d) the International Trademark Association (*INTA*) has submitted its opinions on plain packaging to various governments since 1994, consistently opposing plain packaging. For instance, in its 2011 submission to the Australian Committee on Health and Ageing on the Australian Tobacco Plain Packaging Bill, INTA commented that "the Tobacco Plain Packaging Bill 2011 is a serious encroachment on the rights of trademark owners and frustrates the ability of trademarks to function properly as a part of free and effective commerce."²³⁷
- (e) Business Action to Stop Counterfeiting and Piracy (*BASCAP*) has stated that plain packaging risks "creating a precedent for extreme restrictions of intellectual property (IP) rights and trademarks" and that "[r]estricting trademarks and branding of products removes a critical element of accountability and responsibility that consumers depend on to make the best choices in the marketplace".²³⁸
- (f) the International Chamber of Commerce (*ICC*) has stated that: "[i]t remains unclear as to whether plain packaging is compatible with a number of the UK's international trade commitments including important WTO intellectual property agreements. With protectionism on the rise, this is not the time for the UK to be testing the limits of international trade law". (Andrew Wilson, Director of Policy at the ICC in the UK); and
- (g) the US Chamber of Commerce has stated that:
 - (i) "We believe it is important to make clear our serious concerns with the prospect that the U.K. government may mandate the destruction of an

industry's legitimate trademark protection and branding – rights long protected under law and treaties... The rule of law and legal certainty are not just very important for the business community. They are vital to ensuring innovation is encouraged and rewarded and meaningful jobs are created";²⁴⁰ and

(ii) in a letter to the Australian government, "[plain packaging would] significantly infringe upon global IP and trademark protections", and be inconsistent with Australia's obligations under TRIPS, the Paris Convention, TBT and the Australia-US Free Trade Agreement.²⁴¹

FREEDOM OF EXPRESSION

- 6.34 Freedom of expression, both to impart and receive communication, is commonly recognised as a cornerstone of democratic society. This fundamental right undoubtedly extends to commercial communications. It is protected in the UK by virtue of Article 10 of the ECHR, the Human Rights Act 1998, Article 11 of the EU Charter of Fundamental Rights and the common law.
- 6.35 JTI acknowledges that this freedom is not an absolute right but that the burden is on HM Government to justify any restriction. HM Government must demonstrate that (a) the measure is rationally connected to the Objectives, (b) there is no less restrictive alternative measures that achieve the same ends and that (c) the deleterious effect of the measure and its salutary effects are proportionate.
- 6.36 **Plain packaging meets none of these tests:** there is no reliable evidence of a rational connection with the Objectives; it does not represent a minimal impairment of JTI's freedom of expression given that alternative, substantially less restrictive solutions are available and other regulatory measures have yet to be commenced; and it is disproportionate.

FREEDOM TO TRADE

- 6.37 Beyond TBT (described at paragraph 6.29 above), the freedom to trade and conduct business are rights protected under English law, as well as under the Treaty on the Functioning of the European Union (*TFEU*), Article 15 of the EU Charter of Fundamental Rights and general principles of EU law. Such freedoms are an essential element of free-market economics that must be exercised under conditions of equality. It includes the freedom to engage in an economic or commercial activity and the freedom to contract.
- 6.38 Infringements of this right are contrary to public policy unless there is a legitimate interest meriting protection and the restraint is reasonable, necessary and proportionate. In this regard, the burden lies again with the DH. As with freedom of expression, it is clear that any proposal to restrict JTI's freedom to trade must satisfy this. Plain packaging fails to do so.

Free movement of goods

- 6.39 Under the umbrella of freedom to trade is also the right to the free movement of goods within the EU. JTI notes in this regard that it manufactures products for the UK market both in the UK and in other EU countries, including Germany.
- 6.40 As a measure affecting the product itself (as opposed to arrangements for its sale), plain packaging clearly falls within the prohibition contained in Article 34 TFEU, without discrimination against imports needing to be shown. Measures infringing the free movement of goods are unlawful as a matter of EU law unless they can be justified. The burden of justifying the interference with the right of free movement of goods, again, lies with the DH. The test of justification, even in public health cases, is a strict one. The DH must show that the measure is:
- (a) suitable to achieve a legitimate objective in a coherent and systematic way;
- (b) necessary (based on coherent evidence) to achieve its objectives;
- (c) the least restrictive way of meeting those objectives; and
- (d) proportionate.
- 6.41 Plain packaging fundamentally fails these tests: there is no reliable evidence that it will achieve the Objectives; substantially less restrictive alternative solutions are available; and it is disproportionate.

7. ALTERNATIVE REGULATORY SOLUTIONS

- 7.1 JTI has demonstrated, through this submission (including reference to leading experts' independent opinions), its commitment to the development of appropriate and proportionate tobacco regulation in the UK.
- 7.2 On the basis of a proper assessment of the options set out in the Consultation, JTI believes that Option 1 (the status quo) is the only appropriate outcome. Neither Options 2 or 3 are appropriate, necessary or proportionate.
- 7.3 Option 3 asks respondents to suggest other changes to current cigarette packaging to achieve the Objectives. Option 3 talks of "an alternative approach to reduce the promotional impact of tobacco packaging", and so the option labours under the same fundamental flaws as the plain packaging proposal. It proceeds on the same misunderstanding of the role of tobacco packaging, namely it assumes that packaging causes people to smoke. As demonstrated above, the evidence shows that this is not the case. Option 3 is inappropriate, and so this Response does not suggest an Option 3 alternative.
- 7.4 JTI's core principles include reducing minors' uptake of smoking, preventing minors from obtaining tobacco products and ensuring that adult smokers are informed about the health risks of smoking. JTI supports the DH in seeking to achieve these goals through appropriate and proportionate regulatory interventions.
- 7.5 We set out below alternative regulatory solutions that are less restrictive, more targeted and proportionate ways to achieve these goals. These solutions are likely to be effective when evaluated against Better Regulation principles. They address the key methods by which minors access tobacco products, and studies exist to support their efficacy: xxxix
- (a) better enforcement including prosecutions, fines and other penalties, to tackle the trade in illicit tobacco products. Given the seriousness of the problem, it is imperative that further enforcement resources are dedicated to it in order to reduce (and try to eliminate) the illicit trade in tobacco products. This should be combined with significant fines and penalties, including prosecutions, to ensure effective deterrence;
- (b) more effective, targeted enforcement of the current regulatory regime, notably (i) enforcement of the licensing regime and minimum sale provisions; and (ii) confiscation of cigarettes;
- (c) alternative legislative measures to tackle youth access to tobacco products, notably by penalising (i) 'proxy purchasing' by adults; and (ii) the under-age purchase of tobacco products;

xxxix Various studies have been completed to assess the efficacy of the suggested solutions, using a range of methodologies. JTI makes no comment on, nor does it endorse the methodology of (or any assertions, statements or conclusions made in) any of the studies referred to in this section of the Response.

- (d) reinforcing retail access prevention measures, such as the 'No ID, No Sale' programme, 'CitizenCard' and retail education (e.g., www.tobaccoretailing.co m); and
- (e) renewal of targeted public information campaigns to quickly and effectively raise the awareness of tobacco control measures, such as negative licensing schemes.

BETTER ENFORCEMENT TO TACKLE THE TRADE IN ILLICIT TOBACCO PRODUCTS

- 7.6 The significant scale, and extremely serious consequences, of the illicit trade in tobacco products in the UK are set out above. JTI acknowledges that efforts to tackle the illicit trade in tobacco products have had significant successes particularly in relation to cigarettes in recent years. However, it is imperative that further enforcement resources are dedicated to the problem to reduce (and try to eliminate) it. Further, enforcement is particularly needed in relation to counterfeit tobacco products and illicit whites. HMRC itself has recognised the need for better enforcement of sanctions available to those involved in the illicit tobacco trade. Given the loss to the UK Exchequer caused by the illicit trade in tobacco products, such efforts are likely to be fiscally positive, as increased tax revenues more than compensate for increased enforcement costs.
- 7.7 In addition, the level of fines and penalties must be sufficiently high and they must be better enforced (both in terms of penalties and prosecutions) in order for them to act as deterrents. Currently, seizure of cash under the Proceeds of Crime Act 2000 can result in a criminal prosecution with a custodial sentence of up to 7 years, which may not be sufficiently high considering the profits involved. Further, of the 218 prosecutions relating to tobacco smuggling that took place during the financial year 2010-11 in the UK, only 133 convictions were made in practice. ²⁴⁶ In relation to retailers, for example, recent experience suggests that while a record of retailers who have been found to be selling illicit product may be kept in order to track offenders against which enforcement action may be taken, where illicit sales are identified, the tendency has been to seize products from the shop and issue the retailer with a warning letter without taking further enforcement action. To be an effective deterrent to other retailers, prosecutions are appropriate in such cases, accompanied by publicity which makes clear that such enforcement is the norm even where a relatively small volume of illicit trade is involved. In the long run, as noted in Professors Zimmerman and Chaudhry's Report, "failure to prosecute retailers caught selling illicit trade products can mean that the UK law is not an effective deterrent". 247

MORE EFFECTIVE AND TARGETED ENFORCEMENT OF THE CURRENT REGULATORY REGIME

7.8 It is essential that comprehensive systems are in place to enforce existing minimum age laws and to ensure that all the available penalties are used where regulations are repeatedly breached. Studies exist which suggest that youth smoking prevalence decreases in communities where strong enforcement measures are consistently applied.²⁴⁸

Enforcement of licensing regime and minimum sale age provisions

- 7.9 The Criminal Justice and Immigration Act 2008 introduced a negative licensing system in England and Wales, with effect from 1 April 2009, whereby retailers face orders prohibiting the sale of tobacco if they persistently sell tobacco products to those under the age of 18. Its provisions operate on a 'three strikes and out' approach. If a retailer is convicted of selling tobacco to a minor three times within two years he may be issued with an order prohibiting him from selling tobacco products either personally or on his premises (a *prohibition order*). As highlighted by JTI's submission in respect of the FTC Document, it has supported the introduction of negative licensing for a number of years, as a measure for addressing the issue of youth smoking.
- 7.10 The success of the negative licensing scheme and minimum age of sale provisions relies heavily upon Trading Standards Officers (*TSOs*) to identify incidences of underage sales/purchase and to take action where non-compliance occurs. TSOs must conduct regular checks to identify those premises that repeatedly breach the minimum age of sale provisions.
- 7.11 TSOs currently carry out 'test purchasing' operations, whereby under 18s are tasked to attempt to buy tobacco products to identify whether a retailer is selling tobacco to youths. 'Test purchasing' can and should be used to inform reviews of enforcement action and aid prosecution. Enforcement action also needs to be measured on a regular basis with rapid information exchange between enforcement officers to determine the most effective means of achieving the goals of the new licensing scheme. Additionally, any enforcement action taken, including prosecutions and fines, should be publicised to act as a deterrent to others.
- 7.12 JTI notes that the power to grant prohibition orders has been infrequently used since the 2008 legislation was introduced. During the period 1 April 2010 to 31 March 2011, local councils in England applied for prohibition orders on only five occasions. Further, fines imposed for breaches of the minimum age of sale provision were less than £500 in approximately 85% of cases. JTI considers that more can be done to deter retailers from selling tobacco products to minors by utilising the penalties available in existing legislation.
- 7.13 HM Government should prioritise its regulatory enforcement by providing TSOs with greater resources and training. This should be consistent throughout England and Wales. JTI considers that in support of this approach the refusals register system, required as part of the 'No ID, No Sale' campaign, could be utilised to enable TSOs to collect data about attempts by minors to purchase product so as to better identify the areas where TSOs should be focusing enforcement attention.
- 7.14 No negative licensing provisions have yet been implemented in Northern Ireland. JTI supports and encourages the introduction and effective enforcement of such provisions in Northern Ireland, in similar terms to those adopted in England and Wales.
- 7.15 JTI notes that it is equally important that comprehensive efforts are made to enforce the additional measures introduced in Scotland (i.e., retailer registration

scheme, penalisation of proxy purchasing and penalisation of the purchase of tobacco products by those under 18).

Confiscation of cigarettes

7.16 An often overlooked provision is Section 7(3) of The Children and Young Persons Act 1933. That provision places a duty on police officers and park-keepers to seize any tobacco product in the possession of any person apparently under the age of 16 smoking in any street or public place. Police powers under this provision can also be exercised by Police Community Support Officers. However, JTI has found no publicly available statistics to indicate that tobacco is being confiscated under Section 7 or, if confiscations are being made, how often. A more consistent use of this power could have an impact on smoking by under-16s, as it removes cigarettes from those who have managed to purchase cigarettes or obtain them through social sources. JTI notes, however, that the legislation needs to be updated to reflect the increase in the legal minimum purchase age.

ALTERNATIVE LEGISLATIVE MEASURES TO TACKLE MINORS' ACCESS TO TOBACCO PRODUCTS

7.17 JTI believes that penalising the proxy purchase of tobacco and the purchase, or attempted purchase, of tobacco products by minors could make a significant contribution to reducing minors' access to tobacco in England, Wales and Northern Ireland. The introduction of such offences was considered by the House of Commons Public Bill Committee and the House of Lords when considering the Criminal Justice and Immigration Bill in 2008, but ultimately these offences have only been adopted in Scotland. ²⁵¹

Penalising 'proxy purchasing' by adults

- 7.18 An offence of proxy purchasing would eliminate a significant loophole in the current UK legislative arrangements given the evidence noted above that negative licensing provisions can easily be overcome by adults purchasing as proxies for youths. Nevertheless, the previous Government gave the following reasons as to why it was not prepared to make such action a criminal offence:
- (a) an offence of proxy purchasing "would be extremely difficult to enforce and therefore be of limited value in the Government's efforts to reduce smoking among young people"; ²⁵² and
- (b) "new laws should generally be grounded on a solid evidence base" and HM Government was "not aware of any hard evidence that the proxy purchasing of tobacco is a common practice". 253
- 7.19 In relation to the extent to which proxy purchasing occurs, Lord Bach, when speaking for the then Government, stated that surveys appear to show that most regular smokers under the minimum age usually obtain tobacco themselves by buying it from shops.²⁵⁴ However, no information was provided as to the survey evidence relied upon.

- 7.20 By contrast, a number of studies exist which suggest that proxy purchasing and other social sources are important sources of tobacco for youth: (a) an NHS survey conducted in 2010 found that 69% of 11 to 15 year old "pupils who smoked" had been given cigarettes. Of those young people classified as regular smokers, 50% regularly bought cigarettes from other people and 89% had asked someone to buy cigarettes on their behalf; and (b) a recent mixed-method systematic review the "Young People's Access to Tobacco" report suggests that interventions targeting visibility and complicity will be most effective in tackling youth access through proxy purchasing, including through a legal ban on proxy-purchasing such as that introduced in Scotland. Scotland.
- 7.21 Providing sufficient resources and training to those charged with enforcing the law, such as TSOs, would significantly address the previous Government's concern that the offence of proxy purchasing would be too difficult to enforce. It is also to be noted that such concerns did not prevent an offence of proxy purchasing of alcohol from being created in England and Wales in 2000.²⁵⁷
- 7.22 In 2008, the previous Government undertook to keep its position on the proxy purchasing of tobacco under review.²⁵⁸ In 2011, the DH stated that it would carefully examine the outcome of the academic review it had commissioned of the evidence available about the primary sources of tobacco for young people.²⁵⁹ That academic review has now been completed. It concluded that evidence suggests proxy purchasing is a significant source of tobacco for minors and suggests that further work should be done to investigate interventions which tackle youth access through proxy purchase.²⁶⁰ JTI would therefore welcome a further review by HM Government in light of this recent evidence.
- 7.23 Penalising proxy purchasing would find support from retailers, as reflected by the Association of Convenience Stores (*ACS*) in its 18 August 2008 response to the FTC Document. A large majority of the British public also back the penalisation of proxy purchasing, with polls conducted in 2008 demonstrating that 87% to 92% of people surveyed supported such a measure. ²⁶¹

Penalising the purchase or attempted purchase, and the consumption, of tobacco products by minors

- 7.24 The previous Government declined to support legislation that would make it an offence for minors to purchase tobacco on the basis that the creation of such an offence would not be in line with its efforts to keep young people outside the criminal justice system. ²⁶²
- 7.25 Concerns about penalising minors are entirely legitimate. However, such concerns should, in our view, be weighed carefully against the importance of tackling youth smoking. Although only few smoking minors obtain tobacco products directly from retailers, a small proportion continue to do so and existing regulation has failed to prevent this conduct.
- 7.26 Further, HM Government has previously recognised that there are circumstances in which penalising the actions of minors can be justified, particularly where such offences are punishable as would be the case here by non-custodial

measures. For example, Section 30 of the Policing and Crime Act 2009 makes it an offence for persons under 18 to persistently possess alcohol in public places. This measure was one of the proposals put forward by the Secretaries of State for Children, the Home Office and the DH in 2008 as part of a plan to take stronger enforcement action in relation to alcohol.²⁶³

- 7.27 Action in this area would bring the law on tobacco purchase into line with the law on alcohol, with both proxy purchasing of alcohol and the purchase of alcohol by under 18s already being illegal in England and Wales, 264 Scotland 265 and Northern Ireland. 266
- 7.28 The burden of preventing minors from getting access to tobacco products should not rest on retailers alone. A proxy purchase offence would help deliver the message that the responsibility for tackling youth smoking also lies with those adults who buy tobacco for minors. At the same time, penalising the under-age purchase of tobacco would encourage minors to take responsibility for their own actions.

REINFORCE RETAIL ACCESS PREVENTION

7.29 Retail access prevention programmes have proven to be an effective way of limiting minors' access to cigarettes. 90% of retailers surveyed after the introduction of CitizenCard, the government-approved proof-of-age scheme, believed there to have been a reduction in under-age sales, and 95% were more confident in asking for ID as a result of the campaign. ²⁶⁷ JTI contributes financially to this programme and over 2.2 million CitizenCards have now been issued. The image below is a JTI-supplied tobacco gantry with 'No ID, No Sale' facia.



Tobacco gantry with 'No ID, No Sale' fascia. Image supplied by JTI.

- 7.30 Studies exist which suggest that sales staff who fail to ask for ID are 173 times more likely to sell tobacco to minors and account for 89% tobacco sales to minors.²⁶⁸ These figures highlight the importance of encouraging and supporting retailers to ask for and check ID.
- 7.31 CitizenCard also operate the 'No ID, No Sale' campaign which was launched in January 2004 to promote and publicise all government-approved proof-of-age

schemes. More than 240,000 'No ID, No Sale' information packs, which include age display posters and guidance on how to respond when faced with customers who are unable to provide proof of age, have been distributed to retailers. The images below form part of the 'No ID, No Sale' pack, which can be used by retailers to display in a prominent position at the shop.

It is illegal to sell tobacco products to anyone under the age of 18





Materials from the 'No ID, No Sale' Pack. Image supplied by JTI.

- 7.32 Minors should not smoke. It is illegal to sell tobacco products to minors. Therefore, certain people seeking to purchase tobacco products can expect to be asked to prove their age, and can expect that retailers will accept only the correct ID. JTI suggests that HM Government takes steps to support such efforts to further build upon their success.
- 7.33 The 'No ID, No Sale' campaign also aims to help retailers record attempted underage purchases in a refusals register. Every time a retailer refuses to serve someone with an age-restricted product it is suggested that a brief description of the incident and the attempted purchaser is recorded in a register. In the 'three strikes and out' environment currently in force, the register enables a retailer to demonstrate to TSOs the extent to which they have refused attempts at purchase by minors.

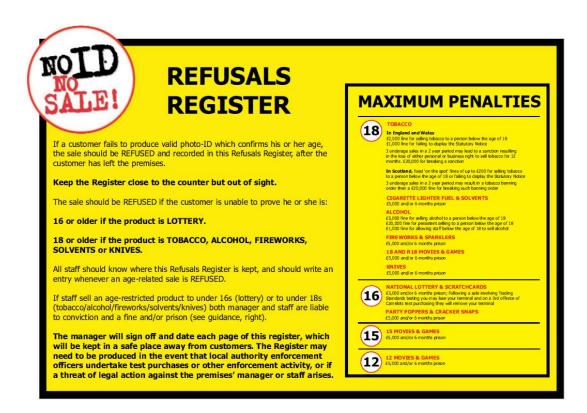


Image of Refusals Register. Image supplied by JTI.

7.34 JTI recommends that HM Government work with the retail community so that attempted underage purchases are recorded in a manner which enables local TSOs to collect data so as to better identify the areas where they should be focusing their attention.

RENEWED PUBLIC INFORMATION CAMPAIGNS

- 7.35 We believe that the goal of discouraging minors from taking up smoking set out in the Consultation should be supported by renewed, government-led public information campaigns, explaining the changes that have recently been made to tobacco control laws and the effect of such measures. Studies suggest that public information campaigns of this nature are an important aspect of successfully implementing retail access prevention measures. If JTI's proposed solutions identified above as regards the proxy/underage purchase are adopted, the impact of such measures would also need to be communicated in this way. This is particularly important in light of concerns that recent changes in UK tobacco regulation, such as the increased minimum age of sale for tobacco, have not been effectively communicated to retailers or the public at large. A May 2008 survey conducted 6 months after the increase in the minimum age found that only 56% of the public knew that the minimum age for the sale of tobacco is 18 years. 270
- 7.36 JTI acknowledges that extensive public information campaigns have been carried out in the UK. Clearly, it is for the DH to determine how to conduct supplementary public information initiatives and the benchmarks by which the success of such campaigns should be measured. JTI notes that the DH has attempted to tailor public information campaigns (for instance, by using particular languages) to

reach out to particular sections of UK society. However, the DH may wish to consider how previous public information campaigns could be renewed or adapted to achieve its stated objective of reaching out to the sections of UK society identified within the Consultation and its accompanying Equality Impact Assessment as being "high smoking prevalence groups". For instance, the Equality Impact Assessment states that "smoking rates are high in other population groups, such as among lesbian, gay and bisexual people", and that "smoking is also higher in certain ethnic groups, in particular Bangladeshi and Pakistani men and Irish men and women". Doing so would be consistent with DH's commitment set out in "Healthy Lives, Healthy People: A Tobacco Control Plan for England" in which DH stated that its communications activities will "reach out to groups with the highest smoking rates, in particular those people with routine and manual jobs". 273

CONCLUSION

- 7.37 For all the reasons stated above, JTI is opposed to plain packaging and calls on the UK Government to take no further action in respect of this regulatory proposal. Put simply, Option 1 is the only credible outcome of the Consultation in light of Better Regulation principles and the fact that:
- (a) there is no evidence that plain packaging will work the DH seeks to change smoking behaviour, but plain packaging will not do this;
- (b) plain packaging is so excessive that its negative effects will be widespread and profound;
- (c) plain packaging unjustifiably infringes fundamental legal rights; and
- (d) less restrictive, more targeted and proportionate alternative solutions are available to tackle legitimate public health objectives.

JTI 3 July 2012

SCHEDULE 1

THE CONSULTATION IA: FUNDAMENTALLY FLAWED

THE REQUIREMENTS THE IA MUST SATISFY

- 1. As described by HM Government, an impact assessment is "[a] tool to be used to help develop policy by assessing and presenting the likely costs and benefits and the associated risks of a proposal that might have an impact on the public, private or third sector, the environment and wider society over the long term". HM Government has published the IA Guidance and the IA Toolkit to assist policymakers to prepare IAs.
- 2. Better Regulation principles require the IA to meet a high threshold, even though it is only at the Consultation stage. As Professor Cave notes, the effort applied at each step of an IA should be "proportionate to the scale of the costs and benefits, outcomes at stake, sensitivity of the proposal and the time available". In a 'first mover' scenario, in particular, "... the absence of direct evidence as to whether a measure like plain packaging actually 'works'... increases the responsibility of the preparer of the [IA] to ensure that the evidence relied upon is objectively reliable and of sufficient quality to justify pursuing the measure. The more draconian or intrusive the measure proposed, the greater the burden on the regulator to ensure this is the case". (Emphasis added.)²⁷⁷ Paragraphs 26 and 27 of the IA Toolkit make the same point, providing that "more data and analysis will be required where the impact is expected to be substantial or fall disproportionately on a specific group".
- 3. Given the severity and the significance of the measure proposed, and its disproportionate impact on specific groups (in particular, tobacco manufacturers), it is particularly important that the IA contains a thorough analysis of all relevant factors, based on reliable evidence.
- 4. The relevant factors in a tobacco control context are identified by Professor Cave as follows:
- (a) "the extent to which alternative means are available to achieve clearly stated public policy goals and objectives, including better enforcement of existing measures and/or the 'do nothing' option;
- (b) the availability of, and the weight which can be assigned to, the evidence base in support of the proposition that the preferred option and other measures would be effective in achieving the stated public policy goals;
- (c) where there are several policy goals, for example in relation to smoking by adults and by minors, the extent to which separate measures may be appropriate;
- (d) the extent and valuation of the health benefits of any measure;

- (e) potential impacts on competition, including any distortionary effects of the proposal;
- (f) distributional impacts, if any, e.g. transfers of income or redistribution of opportunities;
- (g) the legal rights potentially engaged by adoption of the proposal (as a matter of national or supranational law), including, for example, intellectual property rights and the right to commercial expression;
- (h) possible beneficial or detrimental unintended consequences (for example, the expected impact on the illicit trade in tobacco products, on tax revenues, on innovation, on international trade, on research and development, or on small and medium sized enterprises in particular); and
- (i) the impact on the autonomous exercise of consumer choice by adults". ²⁷⁸

THE INADEQUACY OF THE IA

- 5. The IA does not meet the assessment burden set by BIS.²⁷⁹ It fails to undertake a rigorous and comprehensive analysis of the proposed measure based on accurate, objective and complete information. The IA failed to achieve a 'Green' ranking from the Government's own regulatory experts, the RPC. The RPC has classified this IA as "Amber", which means it has "areas of concern that should be corrected". ²⁸⁰
- 6. In particular, the RPC stated in relation to impact on businesses that "Although no monetised impacts of the proposal are provided, the IA says that it is expected that the proposal will have a "neutral effect". Given the proposal is a restriction on business, the IA would benefit from further explaining why this is considered to be the case so that this assumption can be more readily tested during consultation."²⁸¹
- 7. This is consistent with the RPC's general observation that the "most common flaw in [the DH's IAs was] that the analysis of wider economic impacts was incomplete. For example, tobacco IAs tended to provide a full analysis of benefits, but failed to estimate the full economic costs to producers and retailers". ²⁸²
- 8. As was the case with the impact assessments that have accompanied previous regulation directed at tobacco products (and most notably those relating to point of sale advertising and the ban on display), the lack of rigorous analysis suggests that the DH may well have already decided to introduce plain packaging of tobacco products, contrary to Better Regulation principles. ²⁸³
- 9. JTI sets out below the key flaws in the IA.

FLAWED EVIDENCE BASE OF THE IA

10. The IA is fundamentally weakened by its reliance on flawed or non-existent evidence that the proposed plain packaging measure would achieve the objectives set

for it by the DH. JTI sets out its specific comments on the evidence base in Section 3 of, and Schedule 2 to, this Response.

FAILURE TO CONSIDER ALTERNATIVE OPTIONS

11. The IA fails to identify or consider alternatives to plain packaging, or the fact that many existing regulatory measures have only just been (or have not yet even been) introduced. These failures are discussed in more detail at paragraphs 2.26 to 2.44 of Section 2, above.

FAILURE TO ANALYSE THE RISKS RELATING TO ILLICIT TRADE

- 12. The IA Toolkit requires IAs to consider whether "proposals affect the rate of crime or crime prevention or create a new offence/opportunity for crime". ²⁸⁴ Disregarding this requirement, the IA only acknowledges that the impact of plain packaging on illicit trade is one of the proposed measure's "main uncertainties", ²⁸⁵ and does not include the risks relating to illicit trade in its analysis "as there is insufficient evidence on which to include analysis in this IA". ²⁸⁶
- 13. This is a significant omission, given the significance and scale of the negative effects that may be expected to result from an increase in the illicit trade in tobacco products, identified at paragraphs 4.4 to 4.9 and 4.16 to 4.30 of Section 4 above.
- 14. It is not enough for the IA to have identified illicit trade as an uncertainty or to fall back on there being "insufficient evidence". It is incumbent on the DH to consider and develop "robust and compelling" evidence on such an important potential impact. The IA therefore remains seriously incomplete. The DH has spent a great deal of time asking individuals and organisations to create evidence on why plain packaging might work but has chosen to do nothing in relation to the extremely significant, and extremely serious, impacts which plain packaging will have on the illicit trade in tobacco products.

FAILURE TO CONSIDER THE 'ACT OF REBELLION' ARGUMENT

15. Despite having raised it as an issue in the FTC Document,²⁸⁷ the DH fails to consider the point that children may be encouraged to take up smoking if plain packaging were introduced, as it could be seen as rebellious. There is no justification for the DH not to even consider – or seek evidence on – whether this may undermine the achievement of the DH's Objectives.

COST TO MANUFACTURERS OF TOBACCO PRODUCTS

- 16. Reducing the regulatory burden to businesses is one of the key objectives of the Coalition Government's strategy on policy making. To this end, the IA Toolkit requires the DH to consider costs to businesses, including particular costs to particular businesses. ²⁸⁹
- 17. The IA either fails to take into consideration a number of significant costs, or adopts an analysis in relation to particular costs which is fundamentally flawed. While some of these costs may be difficult to express in monetary terms, the Green

Book states that the material costs and benefits that cannot be assessed in monetary terms should clearly be taken into account in evaluating a policy measure. In fact, if the impacts are uncertain, greater efforts are necessary in order to understand the risks as completely as possible. ²⁹⁰ In particular:

- (a) The IA considers that manufacturers' inability to brand their products is a cost saving. While JTI accepts that some reduction in spending may be expected, this cannot be considered a 'saving'. For the reasons set out at paragraphs 5.14 to 5.20 above, the ability to brand is fundamental to all companies, including JTI, and so depriving JTI of that ability should not be considered a cost saving. The damage that the manufacturers will suffer as a result of the loss in their ability to brand will far outweigh any money saved. The IA's conclusion that any such loss will be neutralised by subsequent cost savings demonstrates a fundamental lack of understanding of the commercial realities of business.
- (b) The IA asserts that the transition costs from a change in the level of consumption or switching between brands will be "negligible". The IA makes this point, without evidence. JTI disagrees with the assertion. Even if JTI were to attempt to transition away from tobacco products, this would require a change in the focus of the entire business, and massive transition costs, such that such a transition is highly unlikely to be feasible.
- (c) The IA fails meaningfully to identify or evaluate the impact on the loss of brand equity. The development of brand equity and goodwill is fundamental to market economies, consumer choice, competition and product innovation. JTI has invested very substantially in its IPRs, brands and products, and JTI's brands are worth billions of pounds. However, the IA's calculation for the loss of brand equity includes only the loss caused by downtrading. It therefore massively underestimates the true loss to JTI, because it fails to reflect:
 - (i) what tobacco product manufacturers' brands are worth;
 - (ii) how these brands are valued; and
 - (iii) the loss to JTI caused by the inability to use its branding and the deprivation of its trade marks.
- (d) The IA claims that tobacco manufacturers would not need to retool their machines in light of an assertion that, in Australia, a minor alteration to the plain packaging legislation meant that retooling was not required.²⁹² Plain packaging legislation may result in significant retooling and associated costs to manufacturers, but, for the reasons set out in Schedule 4, JTI is unable to say more in this Response.
- 18. This demonstrates a fundamental failure to understand the business of tobacco product manufacturers.
- 19. The IA's figure of £1.9m as the total industry-wide loss associated with the industry's brands is therefore a completely unrealistic estimate of the true loss.

COSTS TO OTHER BUSINESSES IN THE SUPPLY CHAIN

- 20. For the reasons set out at paragraphs 5.4 to 5.8 above, businesses across the whole of the supply chain, such as those involved in design, origination, production, engraving, embossing and creasing, will be negatively impacted by plain packaging.
- 21. The IA adopts a cursory analysis, and, without evidence, assumes both that those businesses will be able to transition to other sectors of the economy, and that the costs of those transitions will be "negligible". This is simply inadequate in light of the requirement on the IA to properly assess the impact on businesses, in particular small businesses (as part of the small firms impact test)²⁹³ and the wider economy (e.g., labour market).²⁹⁴
- 22. JTI believes that many businesses within the supply chain will be unable to transition easily, and at best will only be able to transition with great difficulty, to other sectors of the economy, leading to significant negative economic effects. In any event, tobacco product packaging is a specialised business, requiring specialist machinery. Such businesses will be forced to write off significant investments made on machinery and R&D. JTI believes that transition costs for such businesses are therefore unlikely to be "negligible".

COST TO RETAILERS

23. The impact on retailers should have been thoroughly assessed as part of the IA. The IA notes an increase in transaction times as a potential cost to retailers. However, the IA wrongly proceeds on the basis that plain packaging will result in reduced transaction times. As noted at paragraph 5.3 above, plain packaging will have significant negative effects on retailers.

IMPACT ON COMPETITION

- 24. The IA Toolkit requires the DH to consider the impacts of its plain packaging proposal on competition. The serious negative effects on competition in the UK tobacco market arising from a plain packaging measure are discussed at paragraphs 5.21 to 5.37 above.
- 25. Whilst the IA does purport to analyse the effect on competition, its analysis is inadequate. In particular:
- (a) it fails to discuss many of the identifiable consequences of a plain packaging measure, including:
 - (i) the effect on brand switching;
 - (ii) the effect on consumer choice;
 - (iii) increased barriers to new entrants; and
 - (iv) market concentration;

- (b) it fails as a consequence to analyse many of the potential effects of a plain packaging measure on competition in the UK tobacco market, in particular:
 - (i) impaired market dynamics; and
 - (ii) lowered quality standards;
- (c) it fails to come to a conclusion on the impact on competition, and instead is limited to highlighting issues, without underlying evidence, and focusing on an analysis of the possible effects on innovation which is itself fundamentally flawed (on which, see below).
- 26. The IA's analysis of competition impacts is fundamentally flawed. It fails to ask the questions demanded by the IA Toolkit, and as a result fails to examine many relevant issues. It also fails to put forward any evidence in support of the few assertions it does make. Considering the seriousness of the proposed competition impacts of a plain packaging measure, it is incumbent on the DH to engage in significantly more analysis of the competition impacts of plain packaging.
- 27. Furthermore, Dr Lilico's analysis of competition effects demonstrates clearly the serious issues raised by plain packaging, and why the DH should not seek to introduce a measure that would produce effects that would not be allowed in other contexts. He concludes that "The increases in concentration are of a scale that would normally be considered of interest and concern to policymakers, as measured on their own standard criteria. Indeed, a key reason competition impacts are assessed in regulatory analysis is to avoid introducing regulations that so vest market power and damage competition."²⁹⁷

IMPACT ON INNOVATION

- 28. The IA Toolkit requires the DH to consider the impacts of its plain packaging proposal on innovation. The serious negative effects on competition and innovation in the UK tobacco market arising from a plain packaging measure are discussed at paragraphs 5.21 to 5.35 above. JTI's view is based on expert evidence from Dr Lilico, who concludes that: "a plain packs requirement would totally eliminate pack innovations. Furthermore, there are many potential innovations in tobacco products that would be rendered all-but infeasible by a plain packs requirement. As well as impeding new innovation (a process that research across many sectors has found can be even more damaging to consumers than damaging competition) this would raise barriers to entry for new brands". 299
- 29. The IA's analysis on innovation is weak and fundamentally flawed. Rather than engaging with the evidence that innovation will suffer as a result of the negative effects on competition in the market, the IA quotes selectively from Dr Lilico's 2008 Report and argues that it is impossible to quantitatively assess the impact of the plain packs measure on innovation.
- 30. Dr Lilico specifically responds to this misrepresentation as follows, at paragraph 4.8 of his 2012 report:

"The quote used in the Impact Assessment was not to be interpreted as indicating that little could be said about effects upon innovation. Rather, the context of that quote was a section entitled "Empirical Evidence on Innovation from other Tobacco Markets" which considered whether data from other jurisdictions could be used as a basis for quantifying impacts on innovation. Since no other jurisdiction had implemented a plain packs requirement, at the time of my 2008 report, there was no data from other jurisdictions to use to address this question and thus it was indeed "impossible to quantitatively assess the impact of the plain packs measure upon innovation" using such data. Australia has adopted a plain packs requirement but it is effective only from 1 December 2012 – thus it remains the case that there is no data available from other jurisdictions on which to base a quantitative assessment of how plain packs requirements have impaired innovation".

31. For the reasons outlined above, plain packaging would totally eliminate pack innovations.

INADEQUATE CONSIDERATION OF IMPACT OUTSIDE ENGLAND

32. Despite purporting to be a UK-wide Consultation, the IA's analysis is predominantly focused on England. The IA itself recognises this gap in analysis.^{xl} The DH must consider the impacts of a plain packaging measure on other parts of the UK.

INADEQUATE ONE IN ONE OUT ANALYSIS

- 33. The IA's One In One Out (*OIOO*) analysis grossly underestimates the direct net cost of the proposed measure as it identifies (and incorrectly estimates) only (a) the costs to retailers and (b) loss of profits to tobacco companies due to down trading "net of saving of expenditure on brand maintenance".³⁰⁰ In particular, it fails to identify the direct costs to tobacco manufacturers that would arise from the proposal, in particular the loss associated with the deprivation of tobacco manufacturers' most valuable assets their brands and trade marks.
- 34. The DH must properly assess all costs and benefits in order to identify the net cost imposed on business in order to comply with the OIOO requirement. The RPC's criticism of the IA echoes this point: "The IA should provide a robust estimate of the Equivalent Annual Net Cost to Business at final stage". ³⁰¹

ADDITIONAL ENFORCEMENT COSTS

35. The IA Toolkit requires that consideration be given to "the expected financial and resource impacts on other Departments". Were plain packaging to be introduced, Government agencies, such as HMRC, the UKBA and the Police, will need to be retrained to distinguish between counterfeit and genuine plain packs. Reliance on authentication equipment is also likely to increase in the absence of the existing visual cues and, therefore, enforcement agencies may have to invest in

The IA states that it considers "costs and benefits of standardised packs for the UK, although some of the illustrative data reported here relate to England only" (IA, paragraph 12).

authentication equipment. JTI is involved in training such agencies and is also likely to incur additional training costs. However, the IA fails to consider these additional costs.

CONSUMER CHOICE

- 36. According to Better Regulation principles, the DH should consider the impact of plain packaging on the consumer and, in particular, consumer choice. The proposal's impact on competition is another key consideration which has a direct impact on consumer choice. 303
- 37. However, the IA fails to include any analysis of the reduction in consumer choice, market concentration/structure changes, price effects and consumer detriment that follow from a plain packaging measure (on which, see the analysis of Dr Lilico referred to at paragraphs 5.18 to 5.37 above).

LACK OF KEY INFORMATION

- 38. The IA states that "the results of the consultation will enable an informed decision to be made on whether or not to proceed with standardised packaging". ³⁰⁴ However, the absence of key information jeopardises the extent to which the respondents can formulate informed responses to assist the DH in the decision making process. In particular:
- (a) the IA only provides a general description as to what plain packs might look like, adding that "details would be set out by the Government in the future". The DH has, however, posed a series of questions in Appendix B, the answers to which require respondents to know precisely those details that will be "set out... in the future". The DH should have provided sufficient information to allow stakeholders to provide meaningful responses to those questions. Without knowing what precisely a plain pack would look like, or the materials from which they are to be constructed, JTI is unable to formulate informed responses to the questions posed by the Consultation;
- (b) a number of underlying sources used in the IA are not disclosed. For instance, Table 1 lists "Information Centre; Anna Gilmore, University of Bath; DH calculations" and does not provide any further information. Similarly, Figure 3 is attributed to "Anna Gilmore, University of Bath" and Figure 4 to "Information Centre". Without access to the underlying data, stakeholders cannot scrutinise the validity of the analysis and evidence put forward in the Consultation and IA. This omission is particularly unfortunate given the DH's specific request (in paragraph 8.3 of the Consultation) to respondents to provide references to research or other evidence with their responses; and

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See "The Green Book, Appraisal and Evaluation in Central Government", HM Treasury, page 9. The EU Impact Assessment Guidelines also indicate that a key question when assessing economic impacts in the context of an IA is whether any options have an impact on consumers, including whether an option has "an impact on the quality and availability of the goods/services they buy, on consumer choice and confidence".

(c) the IA fails to identify what is meant to be included in various of the factors it identifies. For instance, in its discussion of consumer surplus, it states, "[c] onsumer surplus, including the issue of self-expression, will be investigated as part of the consultation", 306 but fails to explain precisely what is meant by, or included within, "the issue of self expression" (beyond commenting that "if lost consumer surplus is seen as the value of individual's freedom to express themselves through their choice of branding"), or how the issue is to be investigated. This makes it impossible for JTI to comment meaningfully on the point raised.

USE OF WRONG OR OUTDATED INFORMATION

- 39. In a number of instances, xlii the IA relies on outdated studies, contrary to the fundamental Better Regulation requirement for "robust and compelling" evidence. Not only are the studies too old to be credible, they were published at a time when the regulatory environment governing the tobacco industry was very different from that of today.
- 40. The IA also makes assertions regarding the role of packaging by reference to a report produced by an advertising agency in 1989.³⁰⁷ The IA presents the advertising agency's view as that of the tobacco industry and does not take into account the fact that the report was produced 23 years ago, in a very different regulatory environment and by an advertising agency in its attempt to win work from a tobacco products manufacturer.

PRACTICAL IMPLICATIONS OF THE FLAWED IA

41. There are serious ramifications of making any decisions about future regulatory measures on the basis of a flawed IA. These have been clearly articulated by the Better Regulation Executive:

"[Regulation] can be ineffective in achieving its intended outcomes if its effects on the system as a whole have not been properly considered. If the details of its proposed implementation have not been thought through at the outset, including the costs on the economy and the potential impact of enforcement, the burden of regulation can be much higher than necessary." 308

- 42. The cumulative effect on the tobacco sector of the flawed impact assessments which have accompanied successive legislative measures underscores the importance of ensuring that a comprehensive assessment is undertaken.
- 43. The DH must comply with the principles of Better Regulation when preparing proposals for legislation. "Robust and compelling" evidence is necessary to support regulatory intervention. It is clear that the IA cannot be used as a basis for the

The IA refers to a number of studies dating back to the early 1990s. The IA, for instance, relies on a study published in 1993, entitled "Smokers' and non-smokers' reactions to standard packaging of cigarettes". Similarly, the IA relies on another 1993 study, entitled "Effects of plain packaging on the image of tobacco products among youth". The IA also refers to studies dating back to 1995, including "When packages can't speak: Possible impacts of plain packaging of tobacco products" and "A study on youth smoking: Plain packaging, health warnings, event marketing and price reductions". See IA, pages 8 and 9.

objective and balanced evaluation of the evidence and costs and benefits of the proposal, since it has been prepared in a fundamentally deficient way that contradicts basic tenets of the UK Government's approach to regulation. As noted by the RPC, "In the absence of any monetisation, the consultation will have to be used to seek additional evidence to provide robust estimates of the net impact of the proposal, particularly on business, at final stage". 309

SCHEDULE 2

ANALYSIS OF THE METHODOLOGY OF THE SYSTEMATIC REVIEW

- 1. JTI discusses below the following limitations of the Systematic Review:
- (a) the 'independence' of the Systematic Review;
- (b) the criteria adopted for a study to be included in the Systematic Review; and
- (c) the fact that conclusions are simply aggregated and repeated.
- 2. This Schedule 2 does not examine the individual studies underlying the Systematic Review (JTI's response on the reliability of these studies is set out in Section 3 of the Response and is informed by the expert reports of Professor Devinney and Dr Keegan at Annexes 8 to 12).

THE 'INDEPENDENCE' OF THE SYSTEMATIC REVIEW IS QUESTIONABLE

- 3. The Systematic Review has been described by some as being "independent". ³¹⁰ JTI is concerned that the Systematic Review is, in fact, inherently biased and self-interested, and does not account for either author or journal partiality.
- 4. The lead author of the Systematic Review is Dr Crawford Moodie. He is reviewing (a) his own work (he authored or co-authored 5 of the 37 studies reviewed) and (b) the work of a network of scholars with whom he interacts with directly and with whom he has co-authored many works. Moreover, the Systematic Review extends gratitude to "Dave Hammond for his contribution to the development of the protocol" who authored or co-authored 7 of the 37 studies reviewed.³¹¹
- 5. Author partiality undermines the Systematic Review. Of the 37 studies cited as "providing evidence of the impacts of plain tobacco packaging". ³¹²
- (a) Professor David Hammond has authored or co-authored 7 out of the 37 studies;
- (b) Dr Crawford Moodie has authored or co-authored 5 out of the 37 studies; and
- (c) Professor Janet Hoek, Dr Allison Ford, Professor Phillip Gendall and Dr Karine Gallopel-Morvan have authored or co-authored 3 studies each of the 37 studies.
- 6. This list alone identifies 6 authors as being responsible for two-thirds of all of the studies included in the Systematic Review.
- 7. A second issue relates to the journals considered as part of the Systematic Review. Although the review is meant to be systematic, it is JTI's view that many of the journals examined are unlikely to publish studies that have findings which are contrary to the overall objective of the journal. For example, of the 37 studies included in the Systematic Review, 20 have been published in a journal and 7 of those

were published in the journal *Tobacco Control*, which has the stated aim of "provid[ing] a forum for research, analysis, commentary, and debate on policies, programmes, and strategies that are likely to further the objectives of a comprehensive tobacco control policy". 313

8. Finally, despite the broad search terms outlined in Appendix 2, the Systematic Review does not appear to have considered the findings set out in the expert reports of Professor Devinney or Dr Keegan, both of which are relevant to the issue of plain packaging and are in the public domain (see JTI's website). Indeed, the original Public Health Research Consortium brief referred to Professor Devinney's 2010 Report. While JTI would not expect these reports to be considered as primary research, their exclusion from the broader search appears to further suggest that the approach adopted in the Systematic Review is at best flawed, and at worst, skewed.

THE APPROACH OF THE SYSTEMATIC REVIEW MEANS INDEPENDENT ANALYSIS IS IMPOSSIBLE

- 9. The Systematic Review is simply a narrative study. It neither achieves the objectives set by the DH, nor is it a 'meta-analysis'. It is not clear what value the Systematic Review can add at all, over and above each of the individual underlying studies it reviews.
- 10. The authors were initially requested by the DH to "produce quantified estimates of the plausible range of impact of plain packaging options upon UK smoking prevalence" and "an analysis of how packaging could drive behaviour change". 315
- 11. In contrast, the authors of the Systematic Review state that the methodology utilised involved conducting a review of studies which met the authors' criteria, after which "data were extracted from each of these [studies] to inform a narrative synthesis organised around five main headings: appeal of cigarettes, packs and brands; salience of health warnings; perceptions of harm; smoking-related attitudes and behaviour; and barriers and facilitators to the introduction of plain packaging". Turther, the authors note that "the possibility of combining the studies statistically in a meta-analysis was explored. Given the diversity of research questions addressed in the included studies, most of which vary on at least four dimensions... it is not appropriate to conduct a qualitative synthesis of these studies". 317
- 12. Instead of providing any statistical analysis as to any impact plain packaging may have on actual smoking behaviour, the authors instead choose to conduct a so-called "thematic summary" of the individual studies, grouping the studies together in terms of their relevance to a certain topic and then drawing their own subjective conclusions on the findings of that group of studies as a whole. In short, the authors have failed in their attempt to produce any quantifiable evidence as to any impact of plain packaging.
- 13. It is therefore important to first consider the initial aim of the Systematic Review against the approach ultimately adopted by the authors. The Systematic Review was limited from the outset in terms of what findings and conclusions it

would be able to reach, and how it would be able to inform the DH's public policy objectives.

- 14. Simply being a "narrative", all of the 'aggregation' and 'analysis' of the findings is based on the considered opinion of the author undertaking the review. A narrative systematic review is therefore akin to a focus group of researchers giving their opinion. In short, there is no way to scientifically test the validity of such a narrative systematic review.
- 15. This view has been repeated by others who have also stated that "the definition of eligibility criteria for trials to be included, a comprehensive search for such trials, and an assessment of their methodological quality are central to systematic reviews. Systematic reviews are thus more likely to avoid bias than traditional, narrative reviews". 319

THE CRITERIA FOR INCLUSION IN THE SYSTEMATIC REVIEW ARE FLAWED

- 16. Separate from the authors' views on the reliability of the individual studies included in the Systematic Review, there are a number of problems with the criteria for study inclusion. This diminishes any weight that would be placed on the Systematic Review.
- 17. Of the 4,518 titles initially identified as being relevant to tobacco packaging, only 37 studies (0.82%) are ultimately included in the Systematic Review. Of these, "23 were surveys (18 of which had an experimental design...), 8 were qualitative studies and two were intervention studies". As set out in Table 4.1 of the Systematic Review ("Characteristics of included studies"), the authors have at least subjectively attempted to account for the different types, and qualities, of studies included. However, this was done holistically and as a criterion for the study to be part of the review. In short, the measurement of 'quality of study' appears to be simply to decide what was included, not how the studies were weighted against one another.
- 18. Other problems with the criteria for inclusion include:
- (a) Studies are included and compared without any real measure of the quality or importance of the studies. For example, one study is included in the Systematic Review as if it were a complete study yet even the authors of the study concede that it is little more than a trial with limited validity. 322
- (b) Studies are assumed to be fully valid and therefore included in the Systematic Review even when the validity of the studies can be questioned based on internationally accepted standards of consumer survey research. For example, of the 23 studies which are said to be survey research, 18 used experimental designs which expert analysis has shown to be of seriously limited validity. JTI further notes that the Systematic Review appears to imply that these studies were included because of their "data analysis" when the reality is that the authors have already conceded that no effective statistical analysis is possible. 325

- (c) Studies are assumed to be valid even in the case where there is no way of determining that validity. For example, eight of the studies were little more than small sample focus groups and two other studies were interview based; yet these were considered to be equally valid to other studies in the discussion.
- (d) Although no study actually measured observed behaviour, Table 4.1 of the Systematic Review incorrectly implies that behaviours were measured though even then it finds that the "overall pattern of findings is mixed". Many statements in the Systematic Review depart from the stated criteria and make predictive statements about behaviour (which is not valid in terms of the studies examined). xliii
- (e) Studies, which exist only in abstract form, are inappropriately included in the Systematic Review. 327 It has previously been noted that "while publication in abstract form is better than no publication at all, the format does not allow the reader to critically assess the findings... since the main purpose of publication is to report a study in detail to allow critical appraisal and decision making on clinical or other questions, neither oral nor "abstract" presentations are considered sufficient to qualify as "complete dissemination"." 328
- 19. Further, the statement made by the authors that "we can be confident that the statements we have made in this review genuinely reflect the current state of research evidence in this area" may be true, but it is a biased and based on low-quality "current state". As discussed by Professor Devinney and Dr Keegan, the studies included in the Systematic Review are so unreliable in terms of their methodology that the findings of the Systematic Review are also compromised. The notion of 'garbage in garbage out' has been discussed by authors in the area of systematic reviews, who have stated that "the quality of component trials is of crucial importance: if the "raw material" is flawed, then the findings of the reviews of this material may also be compromised... clearly, the trials included in systematic reviews and meta-analyses should ideally be of high methodological quality and free of bias...". 330

CONCLUSIONS ARE SIMPLY AGGREGATED AND REPEATED

- 20. The Systematic Review states that its aim is to "assess the impact of plain tobacco packaging on the (i) appeal of the packaging or product, (ii) salience and effectiveness of the health warnings; and (iii) perceptions of product strength and harm". This is different from the Objectives identified as the basis for plain packaging in the Consultation.
- 21. Existing literature suggests that it is important for a systematic review to have a clear and identifiable model that is the basis for what is being examined.³³² The stated purpose of the Systematic Review is to "inform responses to this consultation and any subsequent policy-making".³³³ In order to inform whether the Objectives as set out in the Consultation are likely to be achieved by plain packaging, the

See, for example, page 87 of the Systematic Review states that "in terms of the potential impact of plain packs on participants' own smoking behaviour, two studies suggest that plain packs may help some smokers to quit". This statement is not supported by the studies examined.

Systematic Review should ideally include a theoretical model that outlines how the various components of a purchasing decision are influenced by (a) the factors of interest (in this case, the packaging) and (b) other important factors (e.g., availability and price, etc.) and then how (a) and (b) might be related (if at all) in a final model.

- 22. Instead, the approach undertaken in the Systematic Review is to simply group the individual studies thematically and allow the authors to reach their own view on the likely impact of plain packaging relating to that theme. However, the Systematic Review focuses heavily on areas which are ultimately irrelevant to the Objectives. By way of example, the authors note that, of the 37 studies included in the Systematic Review, "28 studies examined whether and how plain packs impact on the appeal of cigarette products, packs and brands". 334 As discussed above, no study included in the review examines actual smoking behaviour.
- 23. The majority of the studies examined relate to a group of researchers applying what are fundamentally overlapping methods of analysis. Indeed, this particular cohort of authors works together frequently, including repeatedly co-authoring studies and as part of a global project on tobacco control. What this implies is that many of the individual studies reviewed are not providing new information but, rather, recycling information and methodologies already found in other studies. In contrast, the authors of the Systematic Review view this consistency as an advantage, stating that "despite these limitations [of the individual studies], it is worth emphasizing the remarkable consistency in study findings regarding the potential impact of plain packaging". Given Professor Devinney's findings that many of these studies mimic the same flawed empirical approach, the consistency of the findings is unlikely to reveal anything at all.
- 24. Ultimately, it is JTI's view that simply aggregating studies that are flawed does not allow one to draw conclusions. In essence, the approach in the Systematic Review allows only for the authors to repeat the conclusions reached in the individual studies. This does not imply any form of validity, or independence from the original findings of the individual studies. From this perspective, the Systematic Review is no different than the individual studies themselves.

SCHEDULE 3

RESPONSES TO APPENDIX A QUESTIONS

Consultation on standardised packaging of tobacco products – response form

a. Please provide your name and contact information:		
Name of respondent:		
Japan T	obacco International (JTI)	
Address of respondent:		
JTI UK Members Hill Brooklands Road Weybridge Surrey KT13 0QU United Kingdom		
Contact email address:		
b.	Does your response relate to:	
	United Kingdom	
	England only	
	Scotland only	
	Wales only	
	Northern Ireland only	
c.	Are you responding:	
	As a member of the public	
	As a health or social care professional	
\boxtimes	On behalf of a business or as a sole trader (go to question d)	

	On behalf of an organisation (go to question e)
d.	If you are responding on behalf of a business, what type is it?
	Tobacco retailer (supermarket)
	Tobacco retailer (convenience store)
	Tobacco retailer (other type of shop or business)
	Specialist tobacconist
	Duty-free shop
	Wholesale tobacco seller
	Tobacco manufacturer
	Retailer not selling tobacco products
	Pharmaceutical industry
	Other (please provide details below)
If 'Other', please tell us the type of business	
e.	If you are responding on behalf of an organisation, what type is it?
e.	If you are responding on behalf of an organisation, what type is it? NHS organisation
e.	
e.	NHS organisation
e	NHS organisation Health charity/NGO (working at national level)
e.	NHS organisation Health charity/NGO (working at national level) Local Authority
e	NHS organisation Health charity/NGO (working at national level) Local Authority Local Authority Trading Standards or Regulatory Services Department
e.	NHS organisation Health charity/NGO (working at national level) Local Authority Local Authority Trading Standards or Regulatory Services Department Local tobacco control alliance
e.	NHS organisation Health charity/NGO (working at national level) Local Authority Local Authority Trading Standards or Regulatory Services Department Local tobacco control alliance Retail representative organisation
e.	NHS organisation Health charity/NGO (working at national level) Local Authority Local Authority Trading Standards or Regulatory Services Department Local tobacco control alliance Retail representative organisation Other type of business representative organisation

f. Do you, or the business or organisation you represent, have any direct or indirect links to, or receive funding from the tobacco industry?	
□ No	
Yes (please describe below)	
If 'Yes', please describe	
JTI is a tobacco products manufacturer.	
g. If you do not wish your response to be identified in the summary report of consultation responses, please tick this box	
Consultation questions	
1. Which option do you favour?	
Do nothing about tobacco packaging (i.e., maintain the status quo for tobacco packaging)	
Require standardised packaging of tobacco products	
A different option for tobacco packaging to improve public health	
If you prefer a different option for tobacco packaging, please describe it	
2. If standardised tobacco packaging were to be introduced, would you agree with the approach set out in paragraphs 4.6 and 4.7 of the consultation?	
☐ Yes	
No	
Do not know or have no view.	
Please provide an explanation for the answer you provided and evidence if available.	

JTI sets out in full its arguments and the evidence underpinning its positions in its response to the Department of Health's consultation on standardised packaging of tobacco products (the *Response*). The summary below should not be read independently of the full Response.

JTI is categorically opposed to the plain packaging of tobacco products. Not only do the Consultation and Impact Assessment demonstrate a fundamentally flawed process, but:

- plain packaging will not work: there is no reliable evidence to support its introduction;
- it will have serious unintended consequences increasing opportunities for criminals behind the illicit trade, negatively affecting consumers, the retail trade and others in the supply chain, competition in the market and the broader economy and will reduce Government revenue; and
- it will infringe legal rights, depriving JTI of its most valuable assets.

Accordingly, JTI does not support the approach set out in paragraphs 4.6 and 4.7 of the Consultation.

3. Do you believe that standardised tobacco packaging would contribute to improving public health over and above existing tobacco control measures, by one or more of the following:

- Discouraging young people from taking up smoking;
- Encouraging people to give up smoking;
- Discouraging people who have quit or are trying to quit smoking from relapsing; and/or

-	Reducing people's exposure to smoke from tobacco products?
	Yes
\boxtimes	No
	Do not know or have no view

Please provide an explanation for the answer you provided and evidence if available

JTI sets out below a summary of various arguments, and references to expert evidence, that are explained in full in its Response, particularly Section 3. This summary should not be read independently of the full Response.

The Consultation and Impact Assessment recognise that policies like this need to be justified by the impact on smoking behaviour. The objectives of the Consultation are listed as "discouraging young people from taking up smoking"; "encouraging people to quit smoking"; "helping people who have quit, or who are trying to quit, to avoid relapse back to smoking"; and "reducing people's exposure to secondhand smoke from tobacco products". The first three objectives seek to change smoking behaviour, the fourth is dependent for its success on the achievement of one or more of the first three objectives. The Department of Health's objectives relate to smoking behaviour, but it has no actual behavioural evidence to rely on.

This has meant that the Department of Health admits in the Impact Assessment that it is being forced to develop evidence to justify plain packaging. To do so, the Department of Health proposes using the "best guess" and "subjective" views of a panel of individuals with a vested interest in the outcome. The panel will "best guess" the quantitative impact of plain packaging. Without explaining why it was not inviting, in a transparent manner, independent experts to come forward, the Department is selecting individuals for whom impartiality, and having no "economic or personal stake in potential findings", was "impractical". This alone is indefensible, but is made worse by the fact that the Department has not even managed to get the "best guess" of these individuals yet.

Even the Systematic Review commissioned by the Department of Health "to point out how plain packaging might work" is fundamentally unsound. Expert analysis of publicly available materials – including the individual studies relied on by the Systematic Review – demonstrates that there is no reliable evidence that plain packaging will work. The review even ignores its own finding that "there are a number of limitations with the plain packaging studies found" (the Systematic Review, page 88). Grouping individual flawed studies into a review which is systematic in name only does not change the fact that the component parts are flawed.

The evidence base is so weak that the Impact Assessment, produced to justify the proposal – and so putting the point at its highest – can only say that there are "plausible scenarios" under which plain packaging "could be effective", and that there is a "possible impact" on consumption.

The Consultation and Impact Assessment are also deficient in frequently relying on evidence from England only, despite the consultation being held out as being UK-wide.

JTI has set out in more detail at Section 3 of its Response its concerns about the lack of evidence provided by the Department of Health to support plain packaging (see particularly paragraphs 3.15 to 3.44).

The Consultation is also based on a misunderstanding of the role of packaging. Leading experts Laurence Steinberg, Professor of Psychology at Temple University, Philadelphia, US; Ravi Dhar, Professor of Management and Marketing at Yale School of Management, New Haven, US; and Stephen Nowlis, Professor of Marketing at Washington University, St. Louis, US, at JTI's request, have given their independent opinions on how the smoking behaviour of adults and minors should best be understood. These experts demonstrate that plain packaging will not be effective in influencing decision-making and smoking behaviour because it incorrectly assumes that packaging causes people to smoke, and that the provision of yet more information about the health risks of smoking will change smoking behaviour. The Department of Health is now ignoring what it has previously said about what causes people to smoke (see paragraph 3.8 of the Department of Health's 2008 consultation on the future of tobacco control). JTI invites the Department of Health to read the views of Professors Steinberg, Dhar and Nowlis, copies of which have been provided with JTI's Response at Annexes 1 and 2.

4. Do you believe that standardised packaging of tobacco products has the potential to:

a.	Reduce the appeal of tobacco products to consumers?
	Yes
\boxtimes	No
	Do not know or have no view
Please	e provide an explanation for the answer you provided and evidence

if available

harmful effects of smoking?

Yes

The Consultation identifies four "mechanisms" (listed in question 4(a) to 4(d)) by which the objectives (listed in question 3, above) might be achieved. The mechanisms are not objectives. Their sole purpose appears to be to construct alternative issues that the Department of Health considers might be addressed by plain packaging. It looks like the Department of Health has set the tests it wants in order to try to get the result it wants. The Department of Health's stated public health objectives relate to smoking behaviour. But it has no actual behavioural evidence to rely on. Lacking such evidence, it has created a series of "mechanisms by which standardised packaging might work", and has presented evidence on those instead. In other words, it appears the Department has tried to shift the goalposts to make its evidence base suffice. But even that evidence is unreliable.

As explained in detail in paragraphs 3.48 to 3.60 of the Response, none of the mechanisms justify plain packaging. The summaries below, in response to questions 4(a) to 4(d), should not be read independently of the full Response.

As to the first mechanism, reducing the "appeal" of tobacco products to consumers per se is not, and cannot be, a self-standing justification for tobacco regulation.

b. produc	Increase the effectiveness of health warnings on the packaging of tobaccoets?
	Yes
\boxtimes	No
	Do not know or have no view
Please if avai	provide an explanation for the answer you provided and evidence lable
flawed f	and "mechanism" is addressed in paragraphs 3.51 to 3.53 of the Response and is procedurally for the reasons given in answer to question 4(a) above. Further, see the expert reports of r Steinberg (Annex 1) and Professors Dhar and Nowlis (Annex 2).
But incre public pe	ports the continued provision of information to consumers about the health risks of smoking. easing the prominence of health warnings on tobacco packaging is not, of itself, a legitimate olicy objective capable of justifying a plain packaging measure as this mechanism does not behavioural change.
tobacco Departm 'visibilit	g' something, particularly something one knows already – such as a health warning on a product – does not necessarily translate into a change in actual smoking behaviour. The ent of Health has not demonstrated convincingly that plain packaging would enhance the y', 'prominence' or 'salience' of health warnings and has not even attempted to demonstrate mechanism would lead to changes in smoking behaviour.
c.	Reduce the ability of tobacco packaging to mislead consumers about the

⊠ No	
Do not know or have no view	
Please provide an explanation for the answer you provided and evidence if available	
Please provide an explanation for the answer you provided and evidence if available	
The third "mechanism" is addressed in paragraphs 3.54 to 3.57 of the Response and is procedurally flawed for the reasons given in answer to question 4(a) above.	
Existing law already prevents the misleading use of packaging for tobacco products. The Consultation provides no explanation of how current tobacco packaging is said to mislead consumers or why the existing law is inadequate.	
No basis at all has been put forward to support this mechanism.	
d. Affect the tobacco-related attitudes, beliefs, intentions and behaviours of children and young people?	
Yes	
⊠ No	
☐ Do not know or have no view	
Please provide an explanation for the answer you provided and evidence if available	
The fourth "mechanism" is addressed in paragraphs 3.58 to 3.60 of the Response and is procedurally flawed for the reasons given in answer to question 4(a) above.	
This mechanism is an imprecise mish-mash of issues and neither the Consultation nor the Impact Assessment explain what this mechanism is intended to address. In any event, expert evidence demonstrates that tobacco packaging is not a predictor of smoking initiation in adults or minors, which undermines any suggestion that this mechanism will change smoking behaviours.	
To the extent that the Department of Health is referring to the goal of 'denormalising' smokers, this is not, and cannot be, a self-standing objective capable of justifying plain packaging. As a policy, it runs counter to the hallmarks of the UK as a democratic society (notably pluralism, tolerance and broadmindedness), lacks any evidential foundation and is arbitrary.	
5. Do you believe that requiring standardised tobacco packaging would have trade or competition implications?	
⊠ Yes	

No
Do not know or have no view

Please provide an explanation for the answer you provided and evidence if available

JTI sets out below a summary of various arguments, and references to expert evidence, that are explained in full in its Response, particularly Sections 5 and 6 and the expert reports of Dr Andrew Lilico (Europe Economics) (Annexes 4 and 5). This summary should not be read independently of the full Response.

Plain packaging will negatively affect investment, trade, jobs and Government revenue

A recent study estimates that the tobacco industry directly employs 5,700 people in the UK, and indirectly supports 66,000 jobs amongst suppliers, wholesalers, distributors and retailers ("TMA factsheet", May 2012). Tax revenue from tobacco contributed £12.1 billion to the UK Exchequer in tax year 2011/12 ("TMA factsheet", TMA, May 2012) and losses from the illicit trade in tobacco products are already put at up to £3.1 billion ("Measuring Tax Gaps", HMRC, September 2011, pages 25 and 26) – a figure that can only increase as plain packaging worsens the illicit trade in tobacco products.

Any change to the packaging of JTI's products that is required as a result of plain packaging risks significant job losses and reductions in income and economic activity in the UK. This is because of:

- large scale 'downtrading' from premium to cheaper legal tobacco products; and
- a shift from the legitimate to the illicit trade.

Plain packaging will also undermine any future investment and innovation by the tobacco sector in packaging, which will have severely detrimental economic impacts on numerous service industries including pack designers, pack manufacturers and printing and ink suppliers.

Since JTI acquired Gallaher Group for the amount of £9.4 billion in 2007 (at the time the largest overseas acquisition ever made by a Japanese company), it has made significant further investments in the UK. Between 2007 and 2014, JTI will have invested over £180 million in its Lisnafillan manufacturing site in Northern Ireland. Further, in 2012 alone, JTI plans to allocate approximately £75 million to (a) development and training of its employees in Northern Ireland; (b) annual salaries into the Northern Irish local economy; (c) spending on UK suppliers of packaging materials; and (d) providing business for over 100 Northern Ireland companies.

The UK is meant to be 'open for business'. According to the Department of Business Innovation and Skills, "[g]rowth is the Government's top priority and every part of Government is focused on it" (see http://www.bis.gov.uk/policies/growth). Plain packaging manifestly disproves that claim.

Plain packaging will damage competition in the market, and all but end innovation

Distinctive product packaging is fundamental to facilitate product choice and competition. It is the primary tool for developing the value of JTI's brands, innovation and non-price competition. Manufacturers and consumers must be able to identify and distinguish products. This is an essential function of packaging and trademarks.

The UK tobacco market is highly competitive. Manufacturers compete and innovate in order to increase market share amongst existing adult smokers. Packaging is one of the essential components of brand competition. Plain packaging will damage competition.

The expert reports of Dr Andrew Lilico, of Europe Economics, indicate that plain packaging is likely to

undermine the competitive process leading to a reduction in consumer choice. Plain packaging would totally eliminate pack innovations. There would be a reduction in consumer choice and a barrier to manufacturers entering the market with new brands on any basis other than price. Dr Lilico has modelled the competition effects formally in a simulation model deploying standard economic theories and mathematical modelling techniques applied to vertical product differentiation, signalling and adverse selection, and using detailed data on the UK tobacco market. His model demonstrates:

- as brand awareness degrades, competition initially becomes fixated on one or two brands for most price segments (damaging within-price-segment competition) and eventually there is large-scale downtrading into lower-quality products;
- for just modest degrees of brand degradation, average prices of tobacco products as a whole (and cigarettes in particular) fall; and
- an increase in market concentration (even for modest degrees of brand awareness degradation) that should normally be considered of interest and concern to policymakers.

On the basis of the current structure of taxation for tobacco products in the UK and considering the effect on competition of a plain packaging measure, JTI is concerned that the resulting market structure will cause a loss of revenue to the Treasury.

Plain packaging would infringe EU and international trade law

International trade is protected within the EU and internationally under the WTO agreements. For the reasons set out in response to question 6 below, plain packaging would infringe fundamental trade laws.

6. Do you believe that requiring standardised tobacco packaging would have legal implications?

\boxtimes	Yes
	No
	Do not know or have no view

Please provide an explanation for the answer you provided and evidence if available

JTI sets out below a summary of various arguments that are explained in full in its Response, particularly in Section 6 and the expert report of Professor Gervais (Annex 7). This summary should not be read independently of the full Response.

A plain packaging measure, if it could be adopted at all, would deprive JTI of its most valuable assets – its brands and trademarks. JTI will question, and where necessary challenge, regulation that is flawed, unreasonable, disproportionate or without evidential foundation.

Plain packaging would infringe fundamental legal rights, including trade mark rights, property rights, freedom of expression and freedom of trade, that are protected under UK, EU and international law (including the WTO Agreements on Trade Related Aspects of Intellectual Property Rights (*TRIPS*) and the Agreement on Technical Barriers to Trade (*TBT*)). Deprivation of property is presumed to be disproportionate and therefore unlawful unless JTI is compensated at the full value of its property.

JTI is not alone in this view. A number of countries which are members of the WTO have repeatedly

argued against Australia's plain packaging legislation, claiming it infringes TRIPS and TBT requirements. Two WTO Members have taken steps towards commencing the dispute settlement procedure at the WTO against the Australian legislation.

The International Chamber of Commerce, US Chamber of Commerce, a European Trademark Association (MARQUES) and many other business and intellectual property organisations have identified concerns about the legality of plain packaging.

	Do you believe that requiring standardised tobacco packaging would have or benefits for manufacturers, including tobacco and packaging ufacturers?
\boxtimes	Yes
	No
	Do not know or have no view
	se provide an explanation for the answer you provided and evidence ailable
should report Gerva	ts out below a summary of its arguments that are explained in full in its Response. This summary I not be read independently of the full Response, as Sections 4, 5 and 6 (as well as the expert s of Professors Zimmerman and Chaudhry (Annex 3), Dr Lilico (Annexes 4 and 5) and Professor is (Annex 7)) identify the 'costs' associated with plain packaging for tobacco product facturers.
good Impac	consultation and Impact Assessment frequently proceed on the basis that plain packaging will be for manufacturers of tobacco products. This is simply not the case. The Consultation and the t Assessment demonstrate a fundamental failure to understand the business of tobacco product facturers.
and S	al to JTI's business are its brands, including premium brands in the UK like Benson & Hedges ilk Cut. JTI has invested heavily in its brands to take market share amongst existing adult ers from competitors, which is reflected in the strong equity of these brands.
brands effect	packaging eradicates branding, and will erode brand equity, most notably in leading, premium s. JTI's premium brands will therefore be particularly affected – they have the most to lose. This would be exacerbated as plain packaging is expected to lead to large-scale 'downtrading' in mer purchasing, which expert evidence suggests will be the case.
8.	Do you believe that requiring standardised tobacco packaging would have or benefits for retailers?
\boxtimes	Yes
	No
	Do not know or have no view

Please provide an explanation for the answer you provided and evidence if available

Retailers have identified four key negative impacts they will experience as a result of plain packaging:

- Australian retailers have said that transaction times will increase as visual pack recognition will be more difficult worsening transaction time problems that have already been reported in larger shops from the introduction of the display ban (see the report prepared by Deloitte for the Alliance of Australian Retailers, available at:
 https://www.australianretailers.com.au/downloads/pdf/deloitte/Potential impact of channel shift.pdf);
- a plain packaging measure is likely to lead to a 'channel shift' from small to large retailers (again, see the Deloitte report for the Alliance of Australian Retailers). This is likely to have two key effects:
 - as tobacco products make up a significant proportion of the turnover of many smaller retailers, plain packaging may have significant cash-flow and credit implications, particularly serious in the current economic (and bank lending) climate; and
 - as tobacco products are a key driver of 'footfall' (sales of other products when a customer enters a shop to purchase tobacco products), plain packaging is likely to lead to a significant loss of turnover more generally, affecting profit and therefore viability for many smaller retailers;
- downtrading from premium to value products may result in lower margins for retailers, without there being any public health benefit. If all smokers, for instance, downtraded to value products, retailers' loss in revenue due to such downtrading would amount to approximately £442 million. The erosion of the competition position that brands afford would very probably result in an increased focus upon price as one of the most important remaining dimensions of competition. Any price drops caused by plain packaging are at odds with the Department of Health's aim of reducing smoking initiation by minors, as it has stated that lower prices generally mean increased availability and greater access for minors to tobacco products (see paragraph 3.76 of the Department of Health's 2008 Future of Tobacco Control Consultation (the *FTC Document*)); and
- retailers are likely to be negatively affected by any growth in the illicit tobacco trade resulting from plain packaging, as local shopkeepers are further undercut by criminal gangs.

JTI's submission on the impact of plain packaging on retailers is set out at paragraph 5.3 of its Response.

9.	Do you believe t	hat requiring stanc	lardised toba	cco packagin	g would
incre	ase the supply of,	or demand for, illic	it tobacco/no	n-duty paid t	obacco in the
Unite	ed Kingdom?				

\boxtimes	Yes
	No
	Do not know or have no view
Please	e provide an explanation for the answer you provided and evidence

if available

JTI sets out below a summary of its arguments, and relevant expert evidence, on the impact of plain packaging on the illicit trade. This summary should not be read independently of the full Response and particular attention should be paid to Section 4 and the expert report of Professors Zimmerman and Chaudhry (Annex 3).

The illicit trade in tobacco products is already an extremely serious problem in the UK. The Consultation recognises this, noting (using conservative assumptions) that 10% of the market for cigarettes, and 46% of the market for roll-your-own tobacco (referred to by the Department of Health as "hand-rolling tobacco"), is illicit (the current upper estimate of HM Revenue & Customs (HMRC) is that 16% of the market for cigarettes, and 50% of the market for roll-your-own tobacco, is illicit) ("Measuring Tax Gaps", HMRC, September 2011, pages 25 and 26). HM Treasury already loses up to £3.1 billion a year in revenue from the illicit trade in tobacco products ("Measuring Tax Gaps", HMRC, September 2011, pages 25 and 26). The Impact Assessment itself acknowledges that even a 1% increase in the market share of non UK duty paid cigarettes would cost around £90 million in lost duty (the Impact Assessment, paragraph 96). But the Consultation fails to analyse properly the effects of plain packaging on illicit trade. This is a serious failing, especially as recent significant UK tax increases have further widened the gulf between the price of legitimate and illicit product.

The expert report of Professors Zimmerman and Chaudhry identifies that plain packaging will worsen the illicit trade in tobacco products, as it will open new opportunities for illicit traders:

- to provide counterfeit tobacco products with plain packaging;
- to offer counterfeit branded packs (perhaps by mimicking legitimate overseas branded packs); and
- to maintain or increase sales of 'illicit whites' and other smuggled products. As defined by HMRC, 'illicit whites' are "cigarettes manufactured for the sole purpose of being smuggled into and sold illegally in another country. They usually do not pay tax in the country where they are made. In most cases illicit whites are produced in countries outside the European Union, smuggled into the UK and sold at a street price of £2.50 to £3.00 per packet".

Plain packs are cheaper and easier to fake than branded ones:

- a uniform pack design removes the need to keep up with the manufacturers' evolving pack innovations and developments, reducing the costs of faking it;
- plain packaging creates economies of scale. Once one plain pack brand is faked, the counterfeiter can reproduce the packaging of each brand on the market with minimum effort; and
- illicit traders are effectively given a blueprint of how to make the pack.

Ironically, while plain packaging makes life easier and cheaper for counterfeiters, it may make life more difficult for those – including HMRC, Trading Standards and the police – who are required to differentiate between genuine and fake packs. Forensic investigation and analysis of packs may become more resource-intensive and time-consuming. This raises the question of where, in the current economic environment, additional resource required to conduct this pack authentication will come from. Plain packs also make it harder for smokers to identify fakes.

Complex health warnings or tax stamps are not an effective deterrent to counterfeiting these much simpler packs. These visible 'anti-counterfeiting' markings are already easily faked and counterfeiters generally only do enough to 'fool the consumer'. Nor are 'track and trace' requirements the answer. These apply only to manufacturers of genuine products (and, even then, not all of them). In addition, these requirements cannot provide the information smokers need to tell if they have bought a fake pack.

Expert analysis also concludes that plain packaging is highly likely to worsen the existing negative

impacts of the already serious and socially damaging trade in illicit tobacco, in particular by:

- normalising criminal behaviour, whilst profiting criminal gangs;
- damaging local communities;
- creating additional harmful effects on smokers: regulators and public health officials in the UK have repeatedly expressed the concern that smokers could be exposed to greater health risks by consuming an illicit product. The "Dodgy Cigs" campaign, jointly run by the Department of Health and HMRC, has warned that "Often manufactured in backstreet factories with no regulations or quality control, cheap cigarettes and tobacco can contain bugs, rat droppings or any other old muck lying around on the floor. Many Dodgy Cigs have also been found to contain much higher levels of cancer-causing chemicals including arsenic and cadmium" (see "What goes into dodgy cigs is criminal",

http://www.dodgycigs.co.uk/index.php?option=com_content&view=article&id=51&Itemid=2);

- causing significant losses to legitimate businesses, including retailers; and
- depriving the UK Government of revenue.

Tobacco is a highly taxed product (tobacco products in the UK are currently amongst the most expensive in the world). With many smokers facing reductions in discretionary income as a result of the economic downturn, if illicit tobacco products become more widespread, the incentive to buy illicit products may increase. The huge profit potential for criminals and the lack of effective deterrents, prosecutions and convictions coupled with the introduction of plain packaging will create the perfect storm.

In addition, as the problem grows in size, and becomes more difficult to counter, more scarce resources will be required to tackle it. It is unclear where these resources will come from (and further taxes on tobacco are not the answer, as they make the underlying problem worse).

As black market tobacco products are often more accessible to those underage, and those from low income groups, plain packaging also risks undermining the key objective of reducing smoking by minors/those groups. A recent Health Select Committee report noted that "Tobacco smuggling has a disproportionate impact on the poor, particularly young smokers" (House of Commons Health Committee, Health Select Committee on Health Inequalities, March 2009, page 8). Therefore, as noted by the HMRC and the UK Border Agency, "The availability of illegal tobacco products undermines public health objectives and impacts on the health of both individuals and wider communities; circumventing health labelling requirements and age of sale restrictions..." (HMRC and UK Border Agency, "Tackling Tobacco Smuggling – Building on Our Success", April 2011).

10. Those travelling from abroad may bring tobacco bought in another country back into the United Kingdom for their own consumption, subject to UK customs regulations.

This is known as "cross-border shopping". Do you believe that requiring standardised tobacco packaging would have an impact on cross-border shopping?

\boxtimes	Yes
	No
	Do not know or have no view

Please provide an explanation for the answer you provided and evidence if available				
JTI's response on cross-border shopping is at paragraph 4.31 of the Response, and in the expert report of Professors Zimmerman and Chaudhry at Annex 3.				
Expert opinion suggests cross-border shopping is likely to increase in a plain packaging environment. The potential consequences of such an increase on lost revenue are serious, as acknowledged by the Consultation itself.				
11. Do you believe that requiring standardised tobacco packaging would have any other unintended consequences?				
⊠ Yes				
□ No				
Do not know or have no view				
Please provide an explanation for the answer you provided and evidence if available				
JTI sets out in full its arguments in its Response, particularly in Section 5. The summary below should not be read independently of the full Response.				
First, plain packaging will have significant negative impacts on consumers.				
As the Prime Minister recognised (the Prime Minister's comment to <i>The Observer</i> , 13 February 2011), adults should be treated like adults and given " <i>more responsibility over their lives</i> ". That is one of the hallmarks of the tolerant, broad-minded and pluralist society which the UK believes itself to be. Plain packaging removes the choice of adult smokers to choose branded packaging, and makes consumers' ability to choose between brands more difficult. It unjustifiably removes and restricts adult choices around a legal product.				
Not only that, but the negative effects on competition of plain packaging will reduce consumer choice, leading to economic detriment to consumers too.				
Secondly, in addition to the negative economic effect on both tobacco manufacturers and retailers, plain packaging will have severely detrimental economic impacts on numerous service industries, including pack designers, pack manufacturers, printing and ink suppliers, as well as causing confusion and disruption for participants in the product supply chain.				
thirdly, plain packaging is likely to lead to a diminished contribution by JTI to the economy and ignals that the UK is not 'open for business'.				
12. Do you believe that requiring standardised tobacco packaging should apply to cigarettes only, or to cigarettes and hand-rolling tobacco? Cigarettes only				

Cigarettes and hand-rolling tobacco				
□ Do not know or have no view				
Please provide an explanation for the answer you provided and evidence if available				
Plain packaging is not appropriate for any tobacco products.				
13. Do you believe that requiring standardised packaging would contribute to reducing health inequalities and/or help us to fulfil our duties under the Equality Act 2010?				
Yes				
⊠ No				
Do not know or have no view				
Please provide an explanation for the answer you provided and evidence if available				
The introduction of a plain packaging measure will, in principle, affect all consumers of tobacco products. As noted above, there is no convincing evidence that plain packaging will affect smoking behaviour generally. Further, JTI is not aware of any evidence which suggests that plain packaging will affect the smoking behaviour of any particular societal group. As such this measure is not likely to contribute to reducing health inequalities.				
However, plain packaging will worsen the illicit trade in tobacco products. As explained in the response to question 9, above, as black market tobacco products are often more accessible to those underage, and to those from low income groups, plain packaging also risks undermining the key objective of reducing smoking by minors/those groups.				
As set out at paragraphs 7.35 and 7.36 of its full Response, JTI considers that the Department of Health may wish to consider how previous public information campaigns could be renewed or adapted to reach out to sections of UK society identified within the Consultation and Equality Impact Assessment as "high smoking prevalence groups".				

14. Please provide any comments you have on the consultation-stage impact assessment. Also, please see the specific impact assessment questions at Appendix B of the consultation document and provide further information and evidence here to answer these questions if you can.

JTI considers the Impact Assessment to be fundamentally flawed. JTI's detailed points on the procedural and substantive flaws are set out in the full Response, particularly Section 2, Schedules 1 and 2, and the expert report of Professor Cave (Annex 6). Various flaws have been identified in responses to questions above, see for example the responses to questions 3 and 4.

In summary, the Impact Assessment:

- relies on a flawed and incomplete evidence base;
- establishes "mechanisms" in such a way as to try and achieve the desired policy;
- fails to evaluate properly the effectiveness of existing regulation;
- fails to consider alternative options;
- fails to address key costs of the proposal; and
- fails to address key timing issues.

15. Please include any further comments on tobacco packaging that you wish to bring to our attention. We also welcome any further evidence about tobacco packaging that you believe to be helpful.

JTI's summaries in response to the questions in this response form should not be read independently from the full Response. That detailed and fully substantiated Response includes, in addition to the extensive citations of relevant evidence, expert reports from Professor Steinberg, Professors Dhar and Nowlis, Professors Zimmerman and Chaudhry, Professor Devinney, Dr Lilico, Professor Cave, Professor Gervais and Dr Keegan at Annexes 1 to 12.

SCHEDULE 4

RESPONSES TO APPENDIX B QUESTIONS

The purpose of this Schedule is to set out JTI's responses to the questions posed in Appendix B of the Consultation.

1. What would be the costs to tobacco and packaging manufacturers of redesigning packs and retooling printing processes if standardised packaging were introduced?

JTI is unable to answer this question, or other questions relating to the costs of manufacturing packaging in respect of plain packaging, for a number of reasons.

First, it is premature, and indeed impossible, to respond to a question on costs to tobacco and packaging manufacturers of an, as yet, imprecise proposal. Posing such a question at this time further highlights the DH's failure to understand the way in which JTI operates its business.

The Consultation does not set out full specifications for 'plain packaging' nor does it state what the packs are intended to look like, were such a measure to be introduced. For example, no information is provided regarding specifications for pack colour, designs, materials, size or shape. To properly respond to this question, JTI would need to review the DH's precise specifications for 'plain packaging'.

Second, the question asked is in respect of "redesigning packs". It is unclear whether this question applies to cigarette packaging only, or also to the packaging of other tobacco products (such as pouches for RYO tobacco). As noted in JTI's main submission, the Consultation is inconsistent in its treatment of cigarette packaging and packaging for other types of tobacco products. For example, the evidence put forward in the Consultation in support of plain packaging relates only to cigarette packaging.

Finally, this question asks for responses in respect of the direct costs to manufacturers of a plain packaging measure. JTI is concerned that the Consultation fails to consider the indirect costs to manufacturers. For example, the flawed IA ignores the loss to tobacco manufacturers, and others in the supply chain, as a result of an increase in illicit trade in tobacco products.

The focus on direct costs (without any other question on indirect wider costs) further underlines the fact that the DH has failed to properly consider all the implications of a plain packaging measure.

2. Would the cost of manufacturing cigarette packs be lower if standardised packaging were introduced, compared with the current cost of manufacturing packs?

For all the reasons given in response to Question 1 above, JTI considers it premature to respond to this question at this time.

3. How often do cigarette manufacturers amend the design of tobacco packaging for brands on the United Kingdom market, and what are the costs of doing so?

The last major global change JTI made to its UK packaging was regulation-led, following the introduction of pictorial health warnings. In addition to the fact that pack design is often mandated by regulation, pack design is fundamental to staying one step ahead of counterfeiters. Therefore, pack design is fundamental to FMCGs. However, the extent and cost of making the changes – i.e., the information sought by the DH in response to this question – is commercially sensitive. Without a better understanding of how this information is to be used, and who it is to be shared with, JTI is not able to provide a response to this question at this time.

4. How many different types of shape of cigarette pack are currently on the United Kingdom market?

JTI considers that this question is inappropriately vague in terms of what is meant by "shape of cigarette pack", and is unwilling to speculate on the DH's definition of "shape". Notably, it is unclear whether the DH is seeking a comprehensive list of all types of standard flip top packs (for example, the use of 'bevel-edges') or of different sizes of packs to accommodate different size cigarettes, or whether the answer being sought is confined to differences in standard rectangular shaped packs and other shaped packs.

However, examples set out in this Response include: Camel Curve and Benson & Hedges bevel-edged packs (see paragraph 6.3 above). At 15 June 2012, JTI has 334 Stock Keeping Units (*SKUs*) for RMC products. There are 7 unique pack types, and on account of different pack sizes, there are a total of 27 variants of those unique pack types. In respect of RYO products, JTI has 68 SKUs, with 5 unique pack shapes.

5. Would retailing services be affected, and if so, why and by how much, if standardised packs were introduced?

Retailers should be the primary focus of consultation on this issue. JTI believes that retailers will be significantly affected by any plain packaging proposal – see paragraph 5.3 of the body of the Response.

6. How could standardised packs be designed to minimise costs for retailers?

Costs caused by plain packaging for retailers will increase as it becomes harder to identify and differentiate between packs and it becomes easier for counterfeiters to produce fakes.

7. Would retailers bear any other costs if standardised tobacco packaging were introduced?

While retailers should be the primary focus of consultation on this issue, JTI believes that plain packaging would cause significant confusion and disruption for participants in the product supply chain, including retailers and wholesalers. Tasks which would have relied upon visual pack recognition, such as re-stocking, shelving and pack

selection at a customer's request, will be more difficult if that point of reference is removed. This may lead to an increase in the administrative burden for retailers due to the added time required to stock gantries in an appropriate manner and/or locate products in response to consumer requests.

- 8. What is the average price of a packet of cigarettes in the following cigarette market segments?
- Premium brands
- Mid-price brands
- Economy brands
- Ultra-low-price brands

The DH has failed to supply definitions of the different price categories and JTI has been unable to precisely replicate the price segments referred to in the IA and Appendix B. JTI uses different price segments when analysing the market. The average retail selling price per 20 cigarettes in 2011 on the basis of Nielsen market data (using JTI price segments) was as follows:

Premium: £6.94

Sub Premium: £6.36

Mid Price: £5.97

Value: £5.44

- 9. What percentage of total cigarette sales in the United Kingdom are in each of the following cigarette market segments?
- Premium brands
- Mid-price brands
- Economy brands
- Ultra-low-price brands

As the DH has failed to supply definitions of the different price categories, JTI has been unable to precisely replicate the different price segments referred to in the IA and Appendix B. JTI uses different price segments when analysing the market. On the basis of Nielsen market data (using JTI price segments), the share of cigarette volume sales (on a cigarette-sticks, not packs, basis) in 2011 was as follows:

Premium: 20.4%

Sub Premium: 3.9%

Mid Price: 42.2%

Value: 33.5%

- 10. How does the total price of cigarettes break down into manufacturing costs, distribution costs, tax, other costs, profits for retailers and profits for the tobacco manufacturer in the following cigarette market segments?
- Premium brands
- Mid-price brands
- Economy brands
- Ultra-low-price brands

The information sought by the DH in response to this question is commercially sensitive. Without a better understanding of how this information is to be used, and who it is to be shared with, JTI is not willing to provide a response to this question at this time. However, JTI notes that (using JTI price segments), 78% of Benson & Hedges Gold (which is a typical pack in the Premium segment with the recommended retail price of £7.47), and 88% of Sterling King Size (which is a typical pack in the Value segment with the recommended retail price of £6.10) is tax (duty plus VAT).

11. Would consumers trade down from higher-priced to lower-priced tobacco products if standardised tobacco packaging were introduced?

As noted in its main submission, JTI's approach to this issue is essentially based on the work undertaken by Dr Andrew Lilico regarding the impact of plain packaging on competition and the tobacco market. His 2008 report was submitted to the DH with the FTC Response. Dr Lilico subsequently reproduces and expands his conclusions through a simulation model, which bears out the findings in his 2008 report (Dr Lilico's 2012 Report).

Dr Lilico's theoretical analysis and simulation model show clearly that competition initially becomes fixated on one or two brands for most price segments and there would ultimately be large-scale downtrading to lower quality/price products. Indeed, this key conclusion is robust and reproduced in all cross-checks undertaken by Dr Lilico in his simulation model. In short, "lower-quality products gain market share at the expense of higher-quality products". 337

JTI believes that plain packaging may also result in consumers trading out of the legal market and into the illegal market.

12. Of the total cigarette market in the United Kingdom, what proportion is sold in cartons rather than in individual packs?

Again, this question is inappropriately vague. In particular, it is unclear what is meant by the term 'carton' (for example, does the DH define carton as containing 40, 100 or 200 cigarettes per carton?).

- "Principles of regulation", BIS, available at http://www.bis.gov.uk/policies/bre/principles-of-regulation.
- "Plain Tobacco Packaging, a Systematic Review", Public Health Research Consortium, Crawford Moodie, Martine Stead, Linda Bauld, Ann McNeill, Kathryn Angus, Kate Hinds, Irene Kwan, James Thomas, Gerard Hastings, Alison O'Mara-Eves, Spring 2012.
- See "Better Regulation", BIS, available at http://www.bis.gov.uk/policies/bre.
- See "*Reducing Regulation Made Simple*", HM Government, available at http://www.bis.gov.uk/assets/biscore/better-regulation/docs/r/10-1155-reducing-regulation-made-simple.pdf.
- ⁵ See "Better Regulation", BIS, http://www.bis.gov.uk/policies/bre.
- ⁶ "Principles of regulation", BIS, available at http://www.bis.gov.uk/policies/bre/principles-of-regulation.
- See in relation to all three principles, "*Principles of regulation*", BIS, available at http://www.bis.gov.uk/policies/bre/principles-of-regulation.
- ⁸ Professor Cave's Report, paragraph 3.16.
- ⁹ "Principles of regulation", BIS, available at http://www.bis.gov.uk/policies/bre/principles-of-regulation.
- Professor Cave's Report, see paragraph 6.13.
- ¹¹ IA, page 3.
- Parliamentary Debate (26 June 2009), available at http://www.publications.parliament.uk/pa/cm200809/cmpublic/health/090625/pm/90625s09 htm.
- Statement by Alan Johnson, UK Secretary of State for Health, during a Parliamentary Question Session. See Hansard – Commons Debates (16 December 2008), Volume 485, Colum 945.
- DH's response to Angela Harbutt's FoIA request in relation to the Systematic Review (27 February 2012) (File Reference RDJ/031/038). See email to Mark Petticrew dated 19 April 2011. DH's response to the FoIA request has not yet been placed on its website.
- ¹⁵ Consultation, paragraph 61.
- Systematic Review, page 88.
- See paragraphs 2.20 to 2.25.
- ¹⁸ IA, paragraph 53.
- See "Expert elicitation of recharge model probabilities for the Death Valley regional flow system", Ming Ye, Karl F. Pohlmann, Jenny B. Chapman, Journal of Hydrology (2008) 354, 102 to 115, available at http://web1.glyfsu.edu/~ye/pdf/paper9.pdf.
- "The Government Chief Scientific Adviser's Guidelines on the Use of Scientific and Engineering Advice in Policy Making", available at http://www.bis.gov.uk/assets/bispartners/goscience/docs/g/10-669-gcsa-guidelines-scientific-engineering-advice-policy-making.pdf, which provide that:
 - "Departments should draw on a range of appropriate expert sources, both within and outside government. The selection of advisers should match the nature of the issue and should be sufficiently wide to reflect the adversity of opinion amongst experts in the appropriate field(s) in a balanced way... When deciding which external sources to consult, departments should encourage those responsible for individual issues to establish new networks continually in order to capture the full diversity of good evidence-based advice... It is important to ensure that working practices are transparent. Departments should ask prospective experts to follow the seven principles of public life as set out by the Committee on Standards in Public Life, which include the obligation to declare any private interests relating to their public duties. As called for in 'The Universal Ethical Code for Scientists', a declaration of conflicts of interest should be made available to anyone who might rely on that advice and made more widely available as appropriate. Departments should judge whether these interests could undermine the credibility or independence of the advice. It is important to recognise that advisers are rarely totally independent as, by the nature of their expertise they will often have an interest in the sector on which they advise. Gathering evidence from a range of experts or from an expert committee ensures a more independent view as, for example, lobbying will become apparent'.
- ²¹ IA, paragraph 95.
- 22 "Principles of regulation", BIS, available at http://www.bis.gov.uk/policies/bre/principles-of-regulation.
- DH's response to Angela Harbutt's FoIA request in relation to the Systematic Review (27 February 2012) (File Reference RDJ/031/038). See email to Mark Petticrew dated 19 April 2011. DH's response to the FoIA request has not yet been placed on its website.
- IA, paragraph 20.
- "The Green Book, Appraisal and Evaluation in Central Government", HM Treasury, paragraph 6.14; and Commission for the Compact, "Consultation and Policy Appraisal Compact Code of Good Practice", paragraph 5.3, available at http://www.voice4change-england.co.uk/webfin-send/26. See page 6 of HM Government's "Code of Practice on Consultation", which states that the Code of Practice should be read in conjunction with Compact's "Consultation and Policy Appraisal".

- ²⁶ IA, paragraph 13.
- ²⁷ Professor Cave's Report, paragraph 3.16(d).
- ²⁸ See the Tobacco and Primary Medical Services (Scotland) Act 2010, sections 5 and 6.
- 29 "RPC Opinion", RPC. The RPC Opinion was made available as a response to a FoIA request and shared on the following website: http://www.handsoffourpacks.com/blog/angela-harbutt-department-of-health-not-fit-for-purpose/.
- ³⁰ See Tables 2.1a to 2.3b of "Smoking, drinking and drug use among young people in England in 2010", Edited by Elizabeth Fuller (a survey carried out for the NHS Information Centre by the National Centre for Social Research and the National Foundation for Educational Research).
- Table 2.3b of *ibid*.
- ³² IA, paragraph 14.
- ³³ IA, paragraph 32.
- "Better Regulation", BIS, available at http://www.berr.gov.uk/bre.
- See, for one of many sources, the first of the Coalition Government's general principles of regulation, available at http://www.bis.gov.uk/policies/bre/principles-of-regulation.
- 36 "IA Toolkit: How to do an Impact Assessment" (the IA Toolkit), HM Government, available at http://www.bis.gov.uk/assets/biscore/better-regulation/docs/i/11-1112-impact-assessment-toolkit.pdf, paragraphs 59 and 60.
- ³⁷ "IA Guidance: When to do an Impact Assessment" (IA Guidance), HM Government, page 22, available at http://www.bis.gov.uk/assets/biscore/better-regulation/docs/i/11-1111-impact-assessment-guidance.pdf.
- Consultation, paragraph 7.1.
- See Operating Principle 4(e) of "*The Coalition Government's principles of regulation*", General Principles, BIS, available at http://www.bis.gov.uk/policies/bre/principles-of-regulation.
- 40 "The Coalition Government's principles of regulation", General Principles, BIS, available at http://www.bis.gov.uk/policies/bre/principles-of-regulation. Also see HM Government, "Impact Assessment Guidance: When to do an Impact Assessment", paragraph 6: http://www.bis.gov.uk/assets/biscore/better-regulation/docs/i/11-1111-impact-assessment-guidance.pdf.
- Consultation, paragraph 2.8.
- ⁴² IA, paragraph 38.
- Principles of Regulation, BIS, available at http://www.bis.gov.uk/policies/bre/principles-of-regulation.
- 44 RPC Report, "Improving Regulation" (March 2012), page 11, available at http://regulatorypolicycommittee.independent.gov.uk/reports.
- See http://www.bis.gov.uk/assets/biscore/corporate/docs/s/10-1058-strategy-for-sustainable-growth.
- "Code of Practice on Consultation", HM Government, page 7, available at http://www.bis.gov.uk/files/file47158.pdf.
- ⁴⁷ See Case C-246/07 *Commission v Sweden* [2010] ECR I-3317.
- See http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2009-5472&language=EN.
- Parliamentary debate (26 June 2009), available at http://www.publications.parliament.uk/pa/cm200809/cmpublic/health/090625/pm/90625s09 htm.
- Letter from Mark Prisk to Andrew Turner of API Group plc, dated 22 May 2012. This was shared with JTI by one of JTI's suppliers.
- ⁵¹ IA, paragraph 18.
- JTI notes that the non-binding "Guidelines for implementation of Article 13" and the non-binding "Guidelines for implementation of Article 11" only state that Parties "should consider" plain packaging.
- JTI's response is available at http://www.jti.com/how-we-do-business/resources/.
- FTC Document, paragraph 3.8.
- FTC Document, paragraph 3.8.
- ⁵⁶ FTC Document, paragraph 3.9.
- 57 FTC Response, 5 September 2008, paragraph 9.29, available at http://www.jti.com/files/8813/3164/0586/jti response uk DoH.pdf.
- FTC Response, paragraphs 3.1 to 3.8.
- See, for example, the Statement by Alan Johnson, UK Secretary of State for Health, during a Parliamentary Question Session. See Hansard Commons Debates (16 December, 2008), Volume 485, Colum 945.
- 60 Consultation, paragraph 6.1.

- 61 Systematic Review, page 5.
- 62 Systematic Review, page 89.
- 63 Systematic Review, page 89.
- 64 Systematic Review, page 89.
- 65 See Written Ministerial Question Response by Alan Johnson MP, the then Secretary of State for Health, December 2008, available at http://www.publications.parliament.uk/pa/cm200809/cmhansrd/cm081209/wmstext/81209m0001 htm.
- 66 Systematic Review, page 89.
- ⁶⁷ IA, page 28.
- 68 Systematic Review, page 88.
- ⁶⁹ Professor Cave's Report, paragraph 6.6.
- Dr Keegan's Report, page 9.
- Dr Keegan's Report, page 9.
- Professor Devinney's 2010 Report, paragraph 2.4 and Professor Devinney's 2012 Report, paragraph 2.4(a).
- Professor Devinney's 2010 Report, paragraph 2.5(a) and Professor Devinney's 2012 Report, paragraph 2.4(a).
- Professor Devinney's 2010 Report, paragraph 2.5(b) and Professor Devinney's 2012 Report, paragraph 2.4(b).
- Professor Devinney's 2010 Report, paragraph 2.5(c) and Professor Devinney's 2012 Report, paragraph 2.4(c).
- ⁷⁶ Professor Devinney's 2012 Report, paragraph 5.3.
- Professor Devinney's 2012 Report, paragraph 5.3.
- Professor Devinney's 2012 Report, paragraph 5.3(c).
- Professor Devinney's 2012 Report, paragraph 2.9.
- Professor Devinney's 2012 Report, paragraph 5.6.
- Professor Devinney's 2012 Report, paragraph 5.7.
- Professor Devinney's 2012 Report, paragraph 5.8.
- Professor Devinney's 2012 Report, paragraph 5.9
- Professor Devinney's 2012 Report, Table 3.
- Professor Devinney's 2010 Report, paragraph 5.6, and Professor Devinney's 2012 Report, paragraph 5.11.
- 86 Systematic Review, page v.
- IA, paragraph 95.
- 88 Systematic Review, page 88.
- 89 Systematic Review, page v.
- 90 Systematic Review, page 89.
- 91 Systematic Review, page 89.
- ⁹² Professor Devinney's 2010 Report, paragraph 5.5(c).
- 93 Systematic Review, page v.
- Professor Devinney's 2010 Report, page 43.
- In this context, see Professor Cave's Report at paragraphs 6.3 to 6.6.
- ⁹⁶ IA, paragraph 119.
- ⁹⁷ IA, page 29.
- ⁹⁸ IA, page 28.
- See Hora, Stephen C., and von Winterfeldt, D., (1997), "Nuclear waste and future societies: A look into the deep future", in Technological Forecasting and Social Change, Vol. 56, Issue 2, pages 155 to 170.
- See Written Ministerial Question Response by Alan Johnson MP, the then Secretary of State for Health, December 2008, available at http://www.publications.parliament.uk/pa/cm200809/cmhansrd/cm081209/wmstext/81209m0001 htm.
- See endnote 20.
- ¹⁰² IA paragraph 129.
- See Camerer, C., and Johnson, E., (1991), "The process-performance paradox in expert judgment: How can experts know so much and predict so badly?" in K. Anders Ericsson and J. Smith (eds), "Toward a general theory of expertise" (pages 195 to 217), Cambridge University Press, Cambridge.

- ⁰⁴ See Hammond, K., (1996), "Human judgment and social policy. Irreducible uncertainty, inevitable error, unavoidable injustice", Oxford University Press.
- See "Decision behaviour Improving expert judgement", Geir Kirkebøen, available at http://www.concept ntnu no/attachments/058 Kirkebooen%20%20-%20Expert%20judgement.pdf.
- See "Expert elicitation of recharge model probabilities for the Death Valley regional flow system", Ming Ye, Karl F. Pohlmann, Jenny B. Chapman, Journal of Hydrology (2008) 354, pages 102 to 115, available at http://web1.gly.fsu.edu/~ye/pdf/paper9.pdf.
- See, for example, (i) Meehl, P. (1986), "Causes and Effects of My Disturbing Little Book", Journal of Personality Assessment, 50: 370-75; (ii) Goldberg, L. (1970), "Man versus Models of Man", Psychological Bulletin, 73:422-432; (iii) Einhorn, H. (1972), "Expert Measurement and Mechanical Combination, Organizational Behavior and Human Performance",7: 86-106; (iv) Dawes, R., Corrigan,B. (1974), "Linear Models in Decision Making", Psychological Bulletin, 81:97; and (v) Einhorn, H., Hogarth, R. (1975), "Unit Weighting Schemes for Decision Making", Organizational Behavior and Human Performance, 13:171-192.
- ¹⁰⁸ IA paragraph 129.
- ¹⁰⁹ IA paragraph 129.
- Professor Cave's Report, paragraph 8.2.
- Professor Cave's Report, paragraph 6.9.
- The OECD's first principle of good regulation (OECD Guiding Principles) concerns issue identification. Furthermore, pages 28 and 29 of the Handbook detail a number of steps that should be taken to clearly "identify the problem" early in the impact assessment process.
- FTC Document, paragraph 3.77.
- See in particular Section 5 of the Consumer Protection from Unfair Trading Regulations 2008, available at http://www.legislation.gov.uk/uksi/2008/1277/regulation/5/made.
- Article 7 of EU Directive 2001/37, implemented in the UK by Regulation 11 of the Tobacco Products (Manufacturer, Presentation and Sale) Regulations 2002, SI 3041/2002, available at: http://www.legislation.gov.uk/uksi/2002/3041/regulation/11/made.
- For example, the Consultation suggests that an objective of the plain packaging proposal is to reduce "perceptions about the likely enjoyment and desirability of smoking": see page 6 of the Consultation.
- "Measuring Tax Gaps" (September 2011), HMRC, pages 25 and 26.
- "Measuring Tax Gaps" (September 2011), HMRC, pages 25 and 26.
- ¹¹⁹ IA, paragraph 77.
- "Tackling tobacco smuggling Building on our success" (April 2011), HMRC and UKBA, available from http://www.hmrc.gov.uk/news/tackling-tobacco.htm.
- Professors Zimmerman and Chaudhry's Report, paragraphs 61 to 64.
- "Written Evidence from HM Revenue & Customs" (August 31, 2011), HMRC, available at http://www.publications.parliament.uk/pa/cm201012/cmselect/cmniaf/writev/fuel/m3.pdf.
- ¹²³ IA, paragraph 75.
- ¹²⁴ IA, paragraph 76.
- ¹²⁵ IA, paragraph 78.
- "Draft Protocol to Eliminate Illicit Trade in Tobacco Products" (April 4, 2012), FCTC, available at http://apps.who.int/gb/fctc/PDF/it5/FCTC COP INB-IT5 5-en.pdf.
- Professors Zimmerman and Chaudhry's Report, paragraphs 310 to 315.
- See further paragraphs 2.33 to 2.35 of the FTC Document.
- Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004, see recitals 3 and 9.
- Professors Zimmerman and Chaudhry's Report, paragraph 302.
- "The Illicit Tobacco Trade Review 2010", JTI, available at http://www.jti.com/files/9013/3061/3057/JTI supplement tobacco smuggling is organised crime.pdf.
- Written Answers to Parliamentary Questions (23 November 2010), available at http://www.publications.parliament.uk/pa/cm201011/cmhansrd/cm101123/index/101123-x htm.
- "Tackling Tobacco Smuggling Together" (November 2008), HMRC, available at http://www.smokefreenorthwest.org/pdf/Tackling Tobacco Smuggling Together.pdf.
- "Tackling Tobacco Smuggling Building on Our Success" (April 2011), HMRC, available at http://customs.hmrc.gov.uk/channelsPortalWebApp/channelsPortalWebApp.portal? nfpb=true& pageLabel= pageLibrary MiscellaneousReports&propertyType=document&columns=1&id=HMCE_PROD1_031246.
- Professors Zimmerman and Chaudhry's Report, Executive Summary and paragraph 424.

- ¹³⁶ Professors Zimmerman and Chaudhry's Report, paragraph 429.
- Professors Zimmerman and Chaudhry's Report, Executive Summary.
- ¹³⁸ Professors Zimmerman and Chaudhry's Report, Executive Summary.
- ¹³⁹ Professors Zimmerman and Chaudhry's Report, Executive Summary and paragraph 430.
- ¹⁴⁰ Professors Zimmerman and Chaudhry's Report, Executive Summary and paragraph 381(b).
- Professors Zimmerman and Chaudhry's Report, paragraph 397.
- Professors Zimmerman and Chaudhry's Report, paragraph 346.
- As a result, both counterfeiters and contraband operators would assume, correctly, that plain packaging would result in a significant increase in demand for illicit products.
- See "Tackling Tobacco Smuggling Building on our Success", HMRC, page 2. The HMRC report names the Tobacco Manufacturers Association as its source (TMA). The TMA webpage with this definition is at: http://www.the-tma.org.uk/policy-legislation/tobacco-smuggling-crossborder-shopping/illicit-whites/.
- Professors Zimmerman and Chaudhry's Report, paragraphs 398 to 400.
- "Defining Illicit Trade", JTI, available at http://www.jti.com/how-we-do-business/anti-illicit-trade/what-is-it/.
- Professors Zimmerman and Chaudhry's Report, paragraph 401.
- ¹⁴⁸ Professors Zimmerman and Chaudhry's Report, paragraph 406.
- Professors Zimmerman and Chaudhry's Report, paragraphs 406 and 408.
- Professors Zimmerman and Chaudhry's Report, paragraphs 386 to 395.
- Professors Zimmerman and Chaudhry's Report, Executive Summary and paragraph 391.
- Minutes of a meeting between IP Australia and Philip Morris held in Geelong, Victoria, Australia (23 September 2009). See also the views expressed at paragraphs 366 to 371, 381 to 385 and 404 to 411 of Professors Zimmerman and Chaudhry's Report.
- Professors Zimmerman and Chaudhry's Report, paragraphs 293 to 299.
- Professors Zimmerman and Chaudhry's Report, paragraph 402.
- ¹⁵⁵ IA, paragraph 77.
- See the article by the Prime Minister in the Guardian (13 February 2011), available at http://www.guardian.co.uk/commentisfree/2011/feb/12/david-cameron-big-society-good.
- See British Brands Group press release of 16 April 2012, available at http://www.britishbrandsgroup.org.uk/the-group/press. The British Brands Group is a non-profit-making membership organisation that represents a number of well-known brand owners in the UK. JTI is not a member, but some other tobacco manufacturers are.
- See report by Deloitte for the Alliance of Australian Retailers, "Plain Packaging and Channel Shift" (June 2011), page 6.
- "Trading Standards Tobacco Control" (Summer 2011), London Trading Standards Authorities, available at http://www.newham.gov.uk/NR/rdonlyres/FA1EC801-7022-491A-9D61-20C7AFE14BD2/0/UASmailshotJuly2011.pdf.
- "Tobacco Industry in the UK", TMA fact sheet, TMA, May 2012.
- Letter from Nude Brands Consulting Ltd to Emily Thornberry MP (25 April 2012). This was shared with JTI by one of its packaging/design agencies.
- Joint letter from Parkside, Chesapeake, Weidenhammer Packaging Group, Amcor and API Group Plc to Mark Prisk MP. This was shared with JTI by one of its packaging manufacturers.
- ¹⁶³ "Tobacco Industry in the UK", TMA fact sheet, TMA, May 2012.
- See www.bis.gov.uk/about.
- "Digital Opportunity, A Review of Intellectual Property and Growth", an independent report by Professor Ian Hargreaves, which was reported to the UK Government in May 2011, paragraph 8.52 (see http://www.ipo.gov.uk/ipreview-finalreport.pdf).
- Joint letter from Parkside, Chesapeake, Weidenhammer Packaging Group, Amcor and API Group Plc to Mark Prisk MP. This was shared with JTI by one of its packaging manufacturers.
- See Dr Lilico's 2008 Report and Dr Lilico's 2012 Report, enclosed as Annexes 4 and 5.
- FTC Document, paragraph 3.76.
- "RPC Opinion," RPC. The RPC Opinion was made available as a response to a FoIA request and shared on the following website: http://www.handsoffourpacks.com/blog/angela-harbutt-department-of-health-not-fit-for-purpose/.
- ¹⁷⁰ Schecter (1927) 40 Harv LR 813.

- Dr Lilico's 2012 Report, Summary, point 6.
- ¹⁷² Dr Lilico's 2012 Report, Summary, point 6(a).
- Dr Lilico's 2012 Report, Summary, point 5 and 6(c).
- Dr Lilico's 2012 Report, Summary, point 5.
- ¹⁷⁵ IA, paragraph 69.
- Dr Lilico's 2012 Report, Summary, point 12.
- 177 The model necessarily adopts various assumptions: see notably paragraph 6.46 and Annex 1 of Dr Lilico's 2012 Report.
- Dr Lilico's 2012 Report, paragraph 7.4.
- Dr Lilico's 2012 Report, paragraph 7.18.
- Dr Lilico's 2012 Report, Summary, point 10.
- Dr Lilico's 2012 Report, Summary, point 10.
- Dr Lilico's 2012 Report, Summary, point 11.
- Dr Lilico's 2012 Report, Summary, point 12.
- Dr Lilico's 2012 Report, paragraph 7.42.
- FTC Document, paragraph 3.76.
- See Recitals (2), (8) and (10) of the Trade Marks Directive and Recital (4) and Article 1(2) of the CTMR.
- See, further, paragraphs 6.21 to 6.33.
- "Communication from the Commission to the Council, the European Parliament and the European Economic and Social Committee Enhancing the enforcement of intellectual property rights in the internal market" COM(2009) 467 final, available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0467:FIN:EN:PDF.
- Council Resolution of 1 March 2010 on the enforcement of intellectual property rights in the internal market (OJ 2010/C 56/01).
- See in this regard Sporrong and Lönnroth v Sweden (1982) 5 EHRR 35; R (o.a.o. Nicholds & Ors) v Security Industry Authority [2006] EWHC 1792 (Admin); James v UK (1986) 8 EHRR 123; Allard v Sweden (2004) 39 EHRR 14; Hentrich v France (1994) 18 EHRR 440; and Lallement v France, application no. 46044/99, available in French only.
- See Sporrong and Lönnroth v Sweden (1982) 5 EHRR 35, at paragraph 63.
- ¹⁹² Article 6(3), Treaty on European Union.
- ¹⁹³ Charter of Fundamental Rights of the European Union, Article 17(1).
- 194 Article 6(1), Treaty on European Union.
- See Section 2(1) of the 1994 Act, which provides that a "registered trade mark is a property right obtained by the registration of the trade mark under [the 1994 Act]" (see further Sections 22 to 27 of the 1994 Act); and Recital (11) of the CTMR, which provides that Community trade marks are "to be regarded as an object of property" (see further Articles 16 to 24). See also the judgment of the UK Court of Appeal in Boehringer Ingelheim Ltd v. Vetplus [2007] ETMR 67, paragraphs 36 and 37.
- See Anheuser-Busch Inc v. Portugal [2007] ETMR 24, page 343 (ECHR, Grand Chamber) at paragraphs 66 to 72; Case C-479/04 Laserdisken ApS v. Kulturministeriet [2006] ECR I-8089 at paragraph 65; Case C-275/06 Productores de Musica de Espana (Promusicae) v. Telefonica de Espana SAU (Grand Chamber) (29 January 2008) [2008] ECR I-0000 at paragraph 62; Smith Kline and French Laboratories Ltd v Netherlands (1990) 66 DR 70 and IRC v Muller & Co's Margarine Ltd [1901] AC 217, 223.
- Case C-89/99 Schieving-Nijstad VOF v. Groeneveld [2001] ECR I-5851, paragraph 35; Case C-49/02 Heidelberger Bauchemie GmbH, [2004] ECR I-6129, paragraphs 19 to 21; and Case C-245/02 Anheuser-Busch Inc v. Budejovicky Budvar, narodni podnik [2004] ECR I-10989, paragraphs 42 and 55 to 57.
- 198 See footnote xxv.
- See, for example, Sections 32(3) and 46 of the 1994 Act.
- See, for example, Article 15 of TRIPS, available at:

 http://www.wto.org/english/tratop e/TRIPS e/TRIPS e.htm (which states that "Members may make registrability depend on use") and Article 19.1 of TRIPS (relating to whether trade marks may be cancelled for non-use), as described in Professor Gervais' Report, paragraphs 21 and 27. See also paragraphs 23 to 26, 28, 30, 31, 33, 57(a), 59, 66, 67 and 106 of Professor Gervais' Report.
- Section 10(4) of the 1994 Act, implementing Article 5(3) of the Trade Marks Directive.
- Article 9(2) of the CTMR.

- Case C-206/01 Arsenal Football Club plc v. Reed [2002] ECR I-10273, paragraphs 48 and 49; Case C-245/02 Anheuser-Busch Inc v. Budejovicky Budvar, narodni podnik [2004] ECR I-10989, paragraph 69; and Case C-17/06 Céline Sarl v. Céline SA [2007] ECR I-7041, paragraph 16.
- Case C-323/09 Interflora Inc v. Marks & Spencer plc [2011] ECR I-0000, paragraphs 60 to 66; Case C-487/07 L'Oréal SA v. Bellure NV [2009] ECR I-5185, paragraph 58; Joined Cases 236/08 to C-238/08 Google France and Google [2010] ECR I-0000, paragraph 77; Case C-558/08 Portakabin Ltd v Primakabin BV [2010] I-0000, paragraph 30. This line of case law reflected some of the Court of Justice's earlier case law in particular: Case C-348/04 Boehringer Ingelheim KG v. Swingward Ltd [2007] I-3391, paragraph 43; Joined Cases C-427/93, C-429/93 and C-436/93 Bristol Myers Squibb v. Paranova [1996] ECR I-3457, paragraph 76; and Case C-337/95 Parfums Christian Dior v. Evora [1997] ECR I-6013, paragraph 45.
- Joined Cases C-427/93, C-429/93 and C-436/93 Bristol Myers Squibb v. Paranova and others [1996] ECR I-3457, paragraph 75; and Case C-235/09 DHL Express France SAS v Chronopost SA [2011] ECR I-0000, paragraph 46.
- Sections 9 to 12 of the 1994 Act; Articles 5 to 7 of the Trade Marks Directive; Article 9, 12 and 13 of the CTMR.
- Case C-17/06 Céline Sarl v. Céline SA [2007] ECR I-7041, paragraph 16; Case C-487/07 L'Oréal SA v. Bellure NV [2009] ECR I-5185, paragraph 58; Joined Cases 236/08 to C-238/08 Google France and Google [2010] ECR I-0000, paragraphs 75, 76; and Case C-558/08 Portakabin Ltd v. Primakabin BV [2010] I-0000, paragraph 26.
- See Section 10(2) of the 1994 Act; Article 5(1)(b) of the Trade Marks Directive; Article 9(1)(b) of the CTMR; and Case C-251/95 Sabel BV v. Puma AG [1997] ECR I-6191, paragraph 24.
- See Section 12(2) of the 1994 Act; Article 7(2) of the Trade Marks Directive; and Article 13(2) of the CTMR. See also Case C-348/04 Boehringer Ingelheim KG v. Swingward Ltd [2007] ECR I-3391, paragraph 45.
- See, amongst other sources, Case C-200/96 *Metronome Musik GmbH v. Music Point Hokamp GmbH* [1998] ECR I-1953, paragraph 21.
- See endnotes 203 and 209 and footnote xxxiv.
- See Section 10 of the 1994 Act, Article 5 of the Trade Marks Directive; and Article 9 of the CTMR. See further Case C-17/06 Céline Sarl v. Céline SA [2007] ECR I-7041; Case C-487/07 L'Oréal SA v. Bellure NV [2009] ECR I-5185, paragraph 58; Joined Cases 236/08 to C-238/08 Google France and Google [2010] ECR I-0000, paragraphs 75, 76; and Case C-558/08 Portakabin Ltd v Primakabin BV [2010] I-0000, paragraph 26. In relation to registered trade mark infringement claims for which the trade mark owner must establish a likelihood of confusion, see, for example, Case C-251/95 Sabel BV v Puma AG [1997] ECR I-06191, paragraph 23, in which the European Court of Justice states that: "the perception of marks in the mind of the average consumer of the type of goods or services in question plays a decisive role in the global appreciation of the likelihood of confusion".
- 213 See Section 10(3) of the 1994 Act; Article 5(2) of the Trade Marks Directive; and Article 9(1)(c) of the CTMR.
- See Section 5 of the 1994 Act; Article 4 of the Trade Marks Directive; and Article 8 of the CTMR.
- See Section 5(4)(a) and Section 47(2)(b) of the 1994 Act; Article 4(4)(c) of the Trade Marks Directive; and Article 8(4) and Article 53(1)(c) of the CTMR.
- Under (for UK trade mark registrations) Section 46 of the 1994 Act and Article 12 of the Trade Marks Directive, and (for CTMs) Article 51 of the CTMR.
- For example, on the basis that their registration was prohibited (for UK trade mark registrations) under Section 3 of the 1994 Act, and (for CTMs) under Article 7 of the CTMR.
- On the basis of Sections 10 and 12(2) of the 1994 Act; Articles 5 and 7(2) of the Trade Marks Directive; and Articles 9 and 13(2) of the CTMR.
- On the basis of Section 5 of the 1994 Act, Article 4 of the Trade Marks Directive and Article 8 of the CTMR.
- See, for example, Recitals (2), (8) and (10) of the Trade Marks Directive, and Recital (4) and Article 1(2) of the CTMR.
- Available at: www.iso.org.
- The UK has the burden of demonstrating that a measure comes within a permitted exception: *United States Gasoline*, Panel Report, WTO Document WT/DS2/R, 20 May 1996, paragraph 6.20.
- Parliamentary Secretary briefing B09/4084, 22 September 2009, authored by Ian Goss, IP Australia; document released under FoIA requests (FoIA 138 of 1660).
- 224 Thailand Restrictions on Importation and Internal Taxes on Cigarettes, Panel Report, DS10/R-375/200, 7 November 1990 (Thailand Cigarettes).
- Thailand Cigarettes, at paragraphs 73 to 74.

- See endnote 217 above in relation to Section 3(4) of the 1994 Act (and Article 3(2)(a) of the Trade Marks Directive).
- See, for example, the Minutes of the TRIPS meeting on 7 June 2011, available at: http://docsonline.wto.org/GEN_searchResult.asp?RN=0&searchtype=browse&q1=%28@meta_Symbol+IPü_CüMü*%29+%26+%28@meta_Title+Council+for+Trade-Related+Aspects+of+Intellectual+Property+Rights%29.
- See, for example, the Minutes of the TBT Meeting on 15 and 16 June 2011, available at: http://www.smoke-free.ca/trade-and-tobacco/wto-secretariat/TBT M 54.pdf.
- See, for example, the Minutes of the TBT Meeting on 15 and 16 June 2011, available at: http://www.smoke-free.ca/trade-and-tobacco/wto-secretariat/TBT_M_54.pdf.
- See http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds434_e htm.
- See http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds435_e htm.
- Joint statement dated 23 April 2012, available at http://www.marques.org/.
- "Talking Retail", 26 April 2012, available at: http://www.talkingretail.com/news/industry-news/plain-packaging-proposals-for-tobacco-will-%E2%80%98damage-business%E2%80%99.
- Parliamentary Secretary briefing B09/4084, 22 September 2009, authored by Ian Goss, IP Australia; document released under FoIA requests.
- See endnote 223.
- See notably INTA's letter to the Canadian Standing Committee on Health (27 April 1994), to the Department of Health and Ageing, Australia (24 February 2004), and to the Australian Committee on Health and Ageing (22 July 2011).
- 237 INTA submission to the Australian Committee on Health and Ageing (22 July 2011), available at http://www.inta.org/Advocacy/Documents/July222011.pdf.
- ²³⁸ BASCAP press release of 16 April 2012.
- ICC UK press release of 16 April 2012, available at http://www.international-chamber.co.uk/press/72-icc-stresses-need-for-wider-perspective-on-plain-packaging.
- Joint statement of the US Chamber of Commerce, the TransAtlantic Business Dialogue, the Emergency Committee for American Trade, the National Association of Manufacturers, the United States Council for International Business and the National Foreign Trade Council (13 April 2012), reported at http://www.prnewswire.co.uk/news-releases/business-groups-issue-statement-expressing-deep-concern-following-announcement-by-her-majestys-government-that-the-united-kingdom-is-starting-a-public-consultation-to-review-the-mandated-destruction-of-trade marks-and-branding-in-147327455.html.
- Letter from Myron Brilliant, Senior Vice President, Chamber of Commerce of the United State of America, dated 26 February 2010, to the Senate Standing Committee on Community Affairs, Australia.
- ²⁴² Casado Coca v. Spain (1994) EHRR 1, paragraphs 33 to 37 (ECHR); Case C-71/02 Herbert Karner [2004] ECR I-3025, paragraphs 50 to 52; and Case C-380/03 Germany v. Parliament and Council [2006] ECR I-11573, paragraphs 154 to 155; and Krone Verlag GmbH & Co KG v. Austria [2006] 42 EHRR 28.
- ²⁴³ See for instance Case C-200/96 Metronome Musik GmbH v Music Point Hokamp GmbH [1998] ECR I-01953.
- See, for some of the many cases on this point, Case C-120/78 Rewe-Zentral v Bundesmonopolverwaltung fuer Branntwein [1979] ECR 649 ('Cassis de Dijon'), paragraph 15 of Cases C-267 and 268/91 Keck and Mithouard [1993] ECR I-6097, and paragraph 35 of Case C-100/05 Commission v Italy [2009] ECR I-519. See also "Oliver on the Free Movement of Goods within the European Union", Peter Oliver, 5th edition, 2010, paragraph 6.94.
- ²⁴⁵ "Tackling Tobacco Smuggling Building on Our Success" (April 2011), HMRC, page 11.
- ²⁴⁶ "*Tobacco: Smuggling*" (27 March 2012), House of Commons Written Answers, Column 1098W, available at http://www.publications.parliament.uk/pa/cm201212/cmhansrd/cm120327/index/120327-x htm.
- ²⁴⁷ Professors Zimmerman and Chaudhry's Report, paragraph 248.
- See, for example, Tutt et al, "Restricting the Supply of Tobacco to Minors", Journal of Public Health Policy (2009) 30, I, 68-82 and Jason et al, "Effects of Enforcement of Youth Access Laws on Smoking Prevalence" (1999), American Journal of Community Psychology, 27(2): 143-160.
- "Tobacco control survey, England 2010/11: A report of council trading standards service activity", a report produced by the Local Government Group for the DH (28 September 2011).
- Children and Young Persons Act 1933, Section 7(5).
- The Tobacco and Primary Medical Services (Scotland) Act 2010, which came into effect on 1 April 2011, has enacted both offences in the following form:

- 5 Purchase of tobacco products by persons under 18
 - (1) A person under the age of 18 who buys or attempts to buy a tobacco product or cigarette papers commits an offence.
 - (2) It is not an offence under subsection (1) for a person under the age of 18 to buy or attempt to buy a tobacco product or cigarette papers if the person is authorised to do so by a council officer or a constable for the purpose of determining whether an offence is being committed under section 4.
 - (3) A council officer or a constable may authorise a person under the age of 18 to buy or attempt to buy a tobacco product or cigarette papers only if satisfied that all reasonable steps have been or will be taken to avoid any risk to the welfare of the person.
 - (4) A person guilty of an offence under subsection (1) is liable on summary conviction to a fine not exceeding level 1 on the standard scale.
- 6 Purchase of tobacco products on behalf of persons under 18
 - (1) A person aged 18 or over who knowingly buys or attempts to buy a tobacco product or cigarette papers on behalf of a person under the age of 18 commits an offence.
 - (2) A person guilty of an offence under subsection (1) is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

The 'standard scale' means the standard scale of maximum fines for summary offences as set out in s.289G of the Criminal Procedure (Scotland) Act 1975. Level 5 is set at £5000.

- 252 Lord Darzi, the Parliament Under Secretary of State to the DH in response to a written question on 7 January 2008.
- Lord Bach speaking for the Government in the House of Lords Debate on the Criminal Justice and Immigration Bill.
- http://www.publications.parliament.uk/pa/ld200708/ldhansrd/text/80312-0005 htm.
- "Smoking, Drinking and Drug Use Among Young People in England 2010", Fuller E. (2011), NHS Information Centre, available at http://www.ic.nhs.uk/webfiles/publications/003 Health Lifestyles/Smoking%20drinking%20drug%20use%2 02010/Smoking drinking and drug use among young people in England 2010 Full report.pdf.
- "Young People's Access to Tobacco: A mixed-method systematic review", Sutcliffe et al (2011), EPPI-Centre report no 1918, EPPI Centre, Institute of Education, University of London http://eppi.ioe.ac.uk/cms/LinkClick.aspx?fileticket=1PIIjiyuv3Y%3d&tabid=33011.
- Licensing (Young Persons) Act 2000: www.opsi.gov.uk/Acts/acts2000/ukpga 20000030 en 1.
- Lord Bach speaking for the Government in the House of Lords Debate on the Criminal Justice and Immigration Bill: www.publications.parliament.uk/pa/ld200708/ldhansrd/text/80312-0002 htm#0803128000005.
- ²⁵⁹ "Healthy Lives, Healthy People: A Tobacco Control Plan for England" (9 March 2011), DH.
- "Young People's Access to Tobacco: A mixed-method systematic review", Sutcliffe et al (2011), EPPI-Centre report no 1918, EPPI Centre, Institute of Education, University of London http://eppi.ioe.ac.uk/cms/LinkClick.aspx?fileticket=1PIIjiyuv3Y%3d&tabid=3301.
- "Tobacco Alliance Results Summary" (May 2008), Populus (http://www.populuslimited.com/tobacco-alliance-smoking-survey-180508 html). The survey was conducted by Populus, a member of the British Polling Council. Populus interviewed a random sample of 1008 adults aged 18+ by telephone between 16 May 2008 and 18 May 2008. Interviews were conducted across Britain and the results have been weighed to be representative of all British adults.
- FTC Document, paragraph 3.93.
- See "Youth Alcohol Action Plan", June 2008: https://www.education.gov.uk/publications/eOrderingDownload/Cm%207387.pdf.
- Section 149 of the Licensing Act 2003.
- Licensing (Scotland) Act 1976, s.68.
- Licensing (Northern Ireland) Order 1996.
- ²⁶⁷ "Corporate Responsibility Review 2004", Gallaher Group plc, page 23.
- ²⁶⁸ Klonoff EA and Landrine H, "Predicting youth access to tobacco: The role of youth versus store-clerk behavior and issues of ecological validity" (2004) Health Psychology, 23:517–524.
- See, for example, Tutt et al, "Restricting the Supply of Tobacco to Minors", Journal of Public Health Policy (2009) 30, I, 68-82 and Jason et al, "Active Enforcement of Cigarette Control Laws in the Prevention of Cigarette Sales to Minors", (1991) JAMA, Vol 26, No 22.

- ²⁷⁰ "Tobacco Alliance Results Summary" (May 2008), Populus (http://www.populuslimited.com/tobacco-alliance-smoking-survey-180508 html). Further detail about this survey is set out at endnote 261 above.
- "Healthy Lives, Healthy People: A Tobacco Control Plan for England", paragraph 2.16, available at http://www.dh.gov.uk/prod consum dh/groups/dh digitalassets/documents/digitalasset/dh 124960.pdf.
- Equality Impact Assessment, page 10.
- "Healthy Lives, Healthy People: A Tobacco Control Plan for England", available at http://www.dh.gov.uk/prod consum dh/groups/dh digitalassets/documents/digitalasset/dh 124960.pdf.
- Impact Assessment Overview, http://www.bis.gov.uk/assets/biscore/better-regulation/docs/i/11-1110-impact-assessment-overview.pdf.
- 275 IA Toolkit, available at http://www.bis.gov.uk/assets/biscore/better-regulation/docs/i/11-1112-impact-assessment-toolkit.pdf.
- ²⁷⁶ IA Guidance, available at http://www.bis.gov.uk/assets/biscore/better-regulation/docs/i/11-1111-impact-assessment-guidance.pdf.
- ²⁷⁷ Professor Cave's Report, paragraph 6.6.
- ²⁷⁸ Professor Cave's Report, paragraph 4.13.
- See the IA Guidance, the IA Toolkit and, more generally, in HM Government's Better Regulation principles.
- See definition of "Amber" in http://regulatorypolicycommittee.independent.gov.uk/wp-content/uploads/2012/03/RPC-Press-Release-8-March-2012.pdf. The RPC scrutinises IAs against the IA Guidance, IA Toolkit, One-in One-out Methodology and HM Treasury's Green Book.
- 281 "RPC Opinion", RPC. The RPC Opinion was made available as a response to a FoIA request and shared on the following website: http://www.handsoffourpacks.com/blog/angela-harbutt-department-of-health-not-fit-for-purpose/.
- "Improving Regulation" (March 2012), RPC, paragraph 2.56:
 http://regulatorypolicycommittee.independent.gov.uk/wp-content/uploads/2012/04/RPC-REPORT-IMPROVING-REGULATION-March-2012-FINAL.pdf.
- "Written Ministerial Statement: Consultation on standardised packaging of tobacco products", DH, available at http://www.parliament.uk/documents/commons-vote-office/April 2012/16-04-12/7-Health-Tobacco-Packaging-Consultation.pdf. See also Consultation, paragraph 7.2: "an open mind at [the consultation stage] about introducing standardised packaging".
- IA Toolkit, paragraph 70(x).
- ²⁸⁵ IA, paragraph 45.
- ²⁸⁶ IA, page 3.
- FTC Document, paragraph 3.77.
- ²⁸⁸ "Reducing Regulation Made Simple", BIS, Section 1.
- ²⁸⁹ IA Toolkit, paragraphs 70(i)-(iii).
- "The Green Book, Appraisal and Evaluation in Central Government", HM Treasury, page 58 and IA Toolkit, page 9.
- ²⁹¹ IA, paragraph 79.
- ²⁹² IA, paragraph 47.
- ²⁹³ "Guidance on Moratorium on New Domestic Regulation for Micro-Businesses and Start-Ups", BIS.
- ²⁹⁴ IA Toolkit, page 16.
- ²⁹⁵ IA, paragraph 48.
- IA Toolkit, paragraph 70(v): "What are the impacts on competition? Will the number or range of suppliers be limited? Will their ability to compete be limited or the incentive to compete vigorously be reduced?".
- ²⁹⁷ Dr Lilico's 2012 Report, Summary point 12.
- ²⁹⁸ IA Toolkit, paragraph 70(vi): "Will proposals impact on innovation...".
- Dr Lilico's 2012 Report, Summary point 5.
- The IA, paragraph 87.
- 301 "RPC Opinion", RPC. The RPC Opinion was made available as a response to a FoIA request and shared on the following website: http://www.handsoffourpacks.com/blog/angela-harbutt-department-of-health-not-fit-for-purpose/.
- ³⁰² IA Toolkit, paragraph 70(vii).
- ³⁰³ IA Toolkit, pages 16 to 17.
- ³⁰⁴ IA, paragraph 38.

- ³⁰⁵ IA, paragraph 62.
- ³⁰⁶ IA, paragraph 83.
- ³⁰⁷ IA, paragraph 9.
- Better Regulation Executive, "Reducing Regulation Made Simple", paragraph 20.
- 309 "RPC Opinion", RPC. The RPC Opinion was made available as a response to a FoIA request and shared on the following website: http://www.handsoffourpacks.com/blog/angela-harbutt-department-of-health-not-fit-for-purpose/.
- See, for example, "GP and Practice Team Bulletin" (27 April 2012), available at http://gp.dh.gov.uk/2012/04/27/consultation-on-tobacco-packaging-launched/.
- 311 Systematic Review, Acknowledgements.
- ³¹² Systematic Review, page I.
- See http://tobaccocontrol.bmj.com/site/about/guidelines xhtml.
- See "Protocol for Plain Tobacco Packaging: A Systematic Review", dated 5 August 2011, paragraph 2.4, available at http://phrc.lshtm.ac.uk/papers/PHRC 006 Protocol.pdf.
- See correspondence released to Angela Harbutt by the Department of Health under a FoIA request.
- ³¹⁶ Systematic Review, page i.
- 317 Systematic Review, page 21.
- Systematic Review, page 21.
- See Egger, M., Dickersin, K., Smith, G. (2008), "Problems and limitations in conducting systematic reviews" in Systematic Reviews in Health Care: Meta-Analysis in Context. Second Edition, BMJ Publishing, 43-68, page 44.
- 320 Systematic Review, page 24.
- 321 Systematic Review, page 24.
- 322 See Munafo, M., Roberts, N., Bauld, L, Ute, L. (2011), "Plain packaging increases visual attention to health warnings on cigarette packs in non-smokers and weekly smokers but not daily smokers", Addiction, 106(8): 1505-1510.
- See, for example, Professor Devinney's 2012 Report, section 2.
- 324 See, for example, Professor Devinney's 2012 Report, section 5, and Professor Devinney's 2010 Report, section 5.
- 325 Systematic Review, page 19.
- 326 Systematic Review, page iv.
- See, for example: (a) White, C., Hammond, D. (2011), "The impact of cigarette pack design & and plain packaging on female youth in Brazil: brand appeal & health-related perceptions". In Public Health in Canada: Innovative partnerships for Action, Canadian Public Health Association (CPHA) 2011 Conference; (b) Hammond, D., Daniel, S. (2011), "Plain Packaging and Smoking Susceptibility Among UK Youth" in SRNT 17th Annual Meeting, Westin Harbour Castle, Toronto, Ontario, February 16-19; and (c) Gallopel-Morvan, K., Moodie, C., Rey, JM (2011), "Demarketing cigarettes through plain cigarette packaging" in Actes du Congres International del'AFM 2010, Universite du Mansm Le Mans, France.
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- 329 Systematic Review, page 88.
- See Egger, M., Dickersin, K., Smith, G. (2008), "Problems and limitations in conducting systematic reviews" in Systematic Reviews in Health Care: Meta-Analysis in Context. Second Edition, BMJ Publishing, 43-68, page 45.
- 331 Systematic Review, page 24.
- 332 See Egger, M., Dickersin, K., Smith, G. (2008), "Problems and limitations in conducting systematic reviews" in Systematic Reviews in Health Care: Meta-Analysis in Context. Second Edition, BMJ Publishing, 43-68, page 45.
- ³³³ Consultation, paragraph 6.1.
- 334 Systematic Review, page 37.
- See "The International Tobacco Control Policy Evaluation Project", available at http://www.itcproject.org/about.
- 336 Systematic Review, page 90.
- Dr Lilico's 2012 Report, paragraph 6.4(b).