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**'BETTER REGULATION' AND CERTAIN TOBACCO
CONTROL MEASURES**

24 November 2010

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1. INTRODUCTION.

- 1.1 My full name is Martin Cave, and I am BP Centennial Professor at the London School of Economics and Political Science for 2010-11. I have also held professorships at Brunel University and the University of Warwick.
- 1.2 The schedule to this report sets out in detail my professional qualifications, my current curriculum vitae and a list of the publications that I have written or edited. However, in summary terms and amongst other areas of expertise, I am an expert in regulatory economics, or the application of economic analysis to regulated sectors or activities. I have specialised knowledge in the design of regulatory policies to achieve economic, and also social, objectives. I also have expertise in the field of regulatory impact assessments (*RIAs*), having prepared (on behalf of a regulator)¹ and assessed (both from an academic perspective and on behalf of those to be regulated) such impact assessments.
- 1.3 I am co-author of *Understanding Regulation* (Oxford University Press, 1999) and co-editor of *The Oxford Handbook of Regulation* (Oxford University Press, 2010). I have advised many regulators in Europe and elsewhere, the European Commission, and several governments on regulatory matters.
- 1.4 I have been requested to prepare this report for Japan Tobacco International (*JTI*). The views expressed are my own.
- 1.5 This report reviews issues which arise in the regulation of the sale of tobacco products. Its starting point is recognition that tobacco is a product with serious health risks. As suggested below, there are thus good grounds for regulation in some forms. However the specification of objectives and choice of intervention require the same thoroughness of analysis and collection of evidence as does regulation of other areas. The report thus attempts to apply the so-called 'better regulation' agenda to certain measures regulating tobacco sales.
- 1.6 Although this report is not intended to be limited to application to any single regulator's proposal or decision-making, the European Commission Health and Consumers Directorate General's 24 September 2010 public consultation document² on the possible revision of the EU Tobacco Products Directive³ provides a useful opportunity to consider the application of better regulation principles to aspects of the regulation of tobacco sales. This Commission

¹ I was the author of the detailed cost-benefit analysis forming part of the report entitled *Independent Review of Competition and Innovation in Water Markets* (April 2009). The then Chancellor of the Exchequer, the Secretary of State for the Environment, Food and Rural Affairs and the Welsh Minister for the Environment, Sustainability and Housing in the UK commissioned me to conduct this independent review of competition and innovation in the water markets in England and Wales. The aim of the review was to recommend changes to the legislation and regulation of the industry in England and Wales to deliver benefits to consumers, particularly the most vulnerable, and the environment through greater competition and innovation. My final report is available at <http://www.defra.gov.uk/environment/quality/water/industry/cavereview/documents/cavereview-finalreport.pdf>.

² http://ec.europa.eu/health/tobacco/docs/tobacco_consultation_en.pdf.

³ Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products (OJ L 194, 18.7.2001, pp 26-35).

document covers a range of topics, only some of which are considered in this report, namely:

- (a) larger health warnings for tobacco products;⁴
- (b) bans on point of sale display of tobacco products; and
- (c) plain packaging for tobacco products.⁵

I refer to these three proposed measures below collectively as ‘the Proposals’.

1.7 Analysis of each of these options - which have variously been considered (and continue to be considered) by regulators⁶ around the world - inevitably raises questions about:

- (a) which forms of regulation are capable of influencing behaviour;
- (b) how regulation should be developed in a targeted and proportionate fashion in light of internationally recognised better regulation principles; and
- (c) whether there are alternative or complementary means of achieving legitimate public policy goals before moving to introduce measures such as the Proposals.

1.8 In light of this, the purpose of this report, and the way in which I have structured it, is as follows. Following this introduction:

- (a) **Section 2** considers how regulation affects individual behaviour. This discusses how regulation can be used to ‘correct’ perceived market failures in various contexts and some of the models of regulation which may be used for this purpose. It is relevant to the report as a whole, given that it highlights issues as to whether the regulator should act in the same way depending if the group whose behaviour is being

⁴ In the context of the EU, the Commission is currently considering increasing the size of mandatory health warnings beyond the size set by the Tobacco Products Directive, which requires that: “*The general warning required pursuant to paragraph 2(a) and the warning for smokeless and oral tobacco products referred to in paragraph 4 shall cover not less than 30 % of the external area of the corresponding surface of the unit packet of tobacco on which it is printed. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with three official languages. The additional warning required pursuant to paragraph 2(b) shall cover not less than 40 % of the external area of the corresponding surface of the unit packet of tobacco on which it is printed. That proportion shall be increased to 45 % for Member States with two official languages and 50 % for Member States with three official languages*” (see Article 5(5)). Currently, combined text and photo warnings shall cover not less than 40 % of the back of the pack (see the Commission Decision of 5 September 2003 on the use of colour photographs or other illustrations as health warnings on tobacco packages, 2003/641/EC (http://eurlex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32003D0641&model=guichett)).

⁵ Plain packaging is described by the European Commission in its September 2010 consultation document as: “*standardis[ing] the appearance of tobacco packaging. Manufacturers would only be allowed to print brand and product names, the quantity of the product, health warnings and other mandatory information such as security markings. The package itself would be plain coloured (such as white, grey or plain cardboard). The size and shape of the package could also be regulated*”.

⁶ In the specific context of this report, I use the word ‘regulator’ also to include a legislator making regulatory changes.

regulated are adults or 'minors',⁷ an important consideration in the context of smoking, and the deterrent effect of measures which seek to criminalise certain types of behaviour (again, an issue of importance to preventing youth smoking).

- (b) **Section 3** outlines the better regulation agenda: in particular it considers the development of different approaches to regulation and the emergence of internationally recognised principles of better regulation. This analysis is of particular importance in the context of this report, given that it leads to the conclusion that all regulatory initiatives, including those proposed in the context of tobacco control, should be developed in a manner consistent with such principles and that the failure to do so can have serious negative impacts.
- (c) **Section 4** discusses certain important consequences which flow from the better regulation agenda. In particular, it considers the importance of a detailed and thorough RIA as a key tool which aids the implementation of the better regulation principles by regulators in any jurisdiction when they consider measures such as the Proposals. The key themes which I develop in this section, such as the importance of the evidence underlying the regulatory process - which in many instances can be thought of as practical articulations of the principles developed in section 3 - are then explored more fully and by specific reference to their relevance to tobacco regulation in the sections which follow.
- (d) **Section 5**, therefore, builds on a theme first developed in sections 3 and 4, namely the need for a regulator clearly to define both the problem to be addressed, and the objectives of the legislation/regulation being proposed to address that stated problem. In this section, therefore, I review the way in which objectives have been stated for certain tobacco regulation measures such as the Proposals. This review is important to assess whether the identification of stated objectives is consistent with the better regulation principles described in section 3; the consequences of this not being done; and the importance of having clearly stated objectives to help ensure that the regulation proposed to achieve the goals is targeted and proportionate. This ultimately provides the context for discussion elsewhere in this report (in particular in sections 8 and 9) which is important to this report's conclusions of whether there are alternative or complementary means of achieving the regulator's stated objective(s) other than by adopting measures such as the Proposals.
- (e) **Section 6** also builds more specifically on a theme developed in sections 3 and 4, namely the importance of the regulator assessing the evidence underlying any proposed regulatory measure (which, as will be seen from my analysis in section 4, is of particular significance when conducting an RIA). As explained in this section, the importance of examining the evidence base is particularly pertinent to tobacco regulation, given that there is not a consensus on the actual or likely impact of some of the regulatory interventions under consideration in this report (and, in particular, the Proposals).
- (f) **Section 7**, once again building on a theme developed in sections 3 and 4 and applying it to the specific context of tobacco regulation, considers the importance of

⁷ In the specific context of this report, I use the word 'minor' to mean anyone under some specified age (normally 16 or 18) for whom it is illegal to purchase/be sold tobacco products; and 'adult' to mean anyone over that specified age who can legally purchase/be sold tobacco products.

the regulator having regard to whether existing regulation has been effectively implemented and is being effectively enforced, and whether the regulation being proposed is capable of being complied with. The section also considers what the consequences may be if such an assessment is not conducted, which may include a market failure simply being replaced by a type of regulatory failure.

- (g) **Section 8** considers how the themes developed in sections 3 to 7 would be of relevance to the RIA which would necessarily have to be conducted by a regulator when considering the Proposals. A key conclusion in this respect is that it is incumbent upon the regulator - as a matter of better regulation principles - to assess whether there are alternative or complementary means of achieving the regulator's stated objectives (which are considered in section 5) before moving to introduce such Proposals. This is particularly pertinent where it may be considered desirable, particularly in the case of adult smokers, to avoid proscriptive solutions which may run the risk of conferring low or uncertain benefits.
- (h) **Section 9**, in light of the conclusion reached in section 8, considers possible alternative or complementary means of achieving the objectives which have been cited for the Proposals. Here I consider why, as a matter of better regulation norms, alternative regulatory solutions (including proxy purchase and youth purchase offences, and negative licensing regimes) should be given serious consideration by a regulator before adopting other measures such as the Proposals.

2. HOW REGULATION AFFECTS INDIVIDUAL BEHAVIOUR.

- 2.1 Tobacco is purchased by individuals through the ordinary market mechanism involving a buyer and a seller. In this instance, some sales are illegal in the interests of the buyer or seller avoiding tax, and existing regulation has the consequence that some purchases are made by proxy (for example, an adult buying for a minor). Despite these special features, the mode of distribution of tobacco products, like most other consumer products, is essentially a market one.
- 2.2 Markets have the well known property that if they are competitive and involve well-informed agents, including well-informed customers, then they have the capacity to enhance social welfare. This proposition goes back to Adam Smith's 'invisible hand' theory and is captured more precisely in the proposition that competitive markets can, in the right conditions, maximise social welfare, defined as the sum of consumer surplus.⁸
- 2.3 However, markets can fail in one of several ways:
 - (a) the consumption of certain products (including, for example, tobacco products) may have an adverse impact on third parties, not taken into account by consumers in their purchasing decisions; this is illustrated by concerns about environmental tobacco smoke. This form of market failure is susceptible to forms of regulation which are not considered further here;
 - (b) the market place may not be competitive, and firms in it may use their market power to restrict output and raise prices. This form of market failure is the subject of competition law and policy and is not considered here;

⁸ See H Varian, *Intermediate Economics*, 1993, pp 299-301.

- (c) consumers may lack all of the information necessary to make optimal purchasing and consumption decisions, either because of properties of the product (e.g. complexity) or of the buyer, or because the seller/manufacturer does not provide it; and
- (d) more controversially (in the sense that there is room for debate about whether this is truly a 'market failure'), consumers may exhibit purchasing preferences which society considers not to be in their own best interests (for example, a preference for fast foods over 'healthier' ones, or for smoking rather than not smoking). In other words, they may be considered to have the 'wrong' preferences.

2.4 In relation to the last two matters of paragraph 2.3 (which form the basis for the discussion in this report) regulation can be deployed in a variety of forms, including:

- (a) a complete ban on the sale of the product in question (such as a ban on the sale of child pornography or machine guns);
- (b) the targeted restriction of access to a particular product (such as the need for a prescription in order to obtain certain medicine);
- (c) the imposition of minimum quality standards which restrict the range of products available (such as a requirement that tyres sold to the public have a minimum tread, or that internet broadband services have a minimum download speed);
- (d) the imposition of taxes, which will make the product in question more expensive to purchasers and thus (normally) restrict consumption (such as the Scandinavian approach to the taxation of alcohol);
- (e) the provision of information to consumers to correct a perceived deficiency in this respect (such as mandatory nutritional information on packaged food, the mandatory introduction of health warnings on cigarette packets, or wider educational campaigns about product use); and
- (f) attempts directly or indirectly to change consumers' tastes (such as attempts to encourage the consumption of 'healthy' foods, the take-up of educational courses or the watching of public service television).

2.5 It must be recognised that the last two elements in paragraph 2.4 may not always be easy to separate. Conceptually, the difference can be seen in the fact that in the case of imperfect information the preferred regulatory solution is to inform the consumer better, whereas in the case of 'wrong tastes' the 'solution' is to substitute the preferences of either the regulator or other intervener for those of even a well-informed consumer.

2.6 As noted above, cigarettes are products with serious health risks. I am not in a position to provide an expert view as to how people assess such risks at the point of consumption, but I recognise that it is likely to be a complex and multi faceted decision-making process which varies depending on the characteristics of the individual.⁹

⁹ See, for example, J Black, 'The role of risk in regulatory processes' in R Baldwin, M Cave and M Lodge (eds.), *The Oxford Handbook of Regulation*, 2010, pp 311-313.

- 2.7 In liberal democracies, a decision by a legislature or government to declare mistaken and over-ride individual tastes by regulation or otherwise is a momentous one.
- 2.8 In the case of minors, it is routinely made, for example by the requirement of compulsory education and in many other ways. In terms of tobacco consumption by minors, the legitimacy of intervention to prevent consumption is acknowledged by representatives of the public health community and tobacco product manufacturers alike.¹⁰ In what follows I will adopt the view that it is legitimate to over-ride the preferences of minors to deny them access to cigarettes.
- 2.9 Adults present a different issue. On the one hand, the serious health risks of smoking for existing adult smokers are widely acknowledged.¹¹ On the other hand, as far as I am aware, in only one country (Bhutan) has access to tobacco products by adults been banned. Although this is open to interpretation, it can - in my view - be taken to reveal a preference in the case of adults for allowing them autonomy, even while they are being subject to information remedies and encouragement to end or reduce consumption of tobacco products¹² or encouragement to use products that may reduce the risks of tobacco-related disease.¹³
- 2.10 In our 1999 book on regulation, Robert Baldwin and I wrote:¹⁴

“It can be contended that even if one accepts the value of consumer protection, there are a number of reasons why one might on occasions want to favour producer rather than consumer protection and accordingly err on the side of under inclusiveness when imposing restrictions on industry. First, if one accepts that rule makers tend to write over-inclusive rules for a number of reasons ... there may be a case for countering this tendency by consciously erring towards under inclusiveness in

¹⁰ See for example the statement on JTI’s website that “*minors should not smoke. It is wrong for minors to smoke, and we do not engage in any activities whatsoever designed to encourage minors to become smokers. Smoking is, and should be, an adult choice*” (http://www.jti.com/cr_home/cr_positions/cr_positions_youth_smoking).

¹¹ A survey conducted by Health Canada in 2000, for example, notes that “*almost nine in ten Canadian adults think that cigarette smoking is a major health problem in Canada. Only two per cent think it is not a health problem*”; see Health Canada, Baseline Surveys: The Health Effects of Tobacco and Health Warning Messages on Cigarettes Packages, November-December 2000 (<http://www.hc-sc.gc.ca/hc-ps/pubs/tobac-tabac/smoking-tabagisme/smoking-tabagisme03-eng.php>).

¹² The last type of policy has been christened ‘liberal paternalism’ in a recent book by C Sunstein and R Thaler, *Nudge: Improving Decisions about Health, Welfare, and Happiness*, 2008. In a passage entitled “*the slippery slope*”, the authors discuss the distinction in the case of smoking between liberal and intrusively paternalistic interventions (pp 236-237). The notion of “nudging” has attracted recent interest in the UK, with the House of Lords Science and Technology Committee having held the first in a series of sessions to look into how far government should adopt the principles of behavioural economics when regulating (<http://www.bbc.co.uk/news/uk-politics-11669664>).

¹³ I understand that, in 2008, the European Commission’s Scientific Committee for Emerging and Newly Identified Health Risks (SCENIHR) published an opinion on the health effects of smokeless tobacco use. The Committee found that, among the major smoking-related diseases, the use of smokeless tobacco poses fewer risks than that of cigarette smoking. See further: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_013.pdf.

¹⁴ R Baldwin and M Cave, *Understanding Regulation*, 1999, p 106.

particular in cases of uncertainty. Second, one might put a value on economic liberty as a good in itself or favour under-inclusiveness where compliance costs are liable to be extremely high and the benefits of the rule are low (a regulation might be proposed in such circumstances for reasons of social justice rather than on efficiency grounds)".

- 2.11 The tension between regulatory strategies based on prohibition and those based upon empowerment is a durable one, which is unlikely ever fully to be resolved. But however the above dilemma is resolved, it is clear to me that a different set of issues has to be addressed in relation to the regulation of smoking by adults than is addressed in relation to minors.

3. THEORIES OF REGULATION AND PRINCIPLES OF BETTER REGULATION.

The development of the better regulation agenda

- 3.1 The growth of regulation has been marked, and remarked upon, at least since the start of the twentieth century. Initially viewed by some as a means of eliminating the market failures and inequities of unbridled capitalism, regulation has itself been identified as having potentially dysfunctional effects on economic development and social welfare, and as an activity susceptible to capture by regulatees.¹⁵
- 3.2 This has led to demands to push back the boundaries of regulation by adopting the explicit goal of deregulation. The objective is often expressed as that of eliminating 'red tape', the pejorative term for costly and unnecessary restrictions on individuals and firms, leading to the loss of freedom and the excessive bureaucratisation of economic and social life. A second policy dynamic has been to accept the inevitability of the survival of some forms of regulation (and possibly of their increase as environmental and sustainability objectives are given greater prominence), and instead to focus on changing their direction and improving their quality.¹⁶
- 3.3 Seen from this perspective, the rise of the better regulation agenda is at worst a rhetorical device which holds out the false prospect of coherence and consistency between the 'red tape' and the 'regulatory quality' objectives, and at best a genuine way of combining them. In my experience of the application of better regulation, it is quite capable of making genuine improvements in regulatory outcomes.
- 3.4 The better regulation agenda was also fuelled by a third dynamic, namely a long-standing interest in introducing 'rational planning' tools into regulatory policy-making and thereby limiting the scope for bureaucratic and political knee-jerk regulation (a frequently cited example being the UK's Dangerous Dogs Act 1991).¹⁷ One key example of such rationalist

¹⁵ See generally R Baldwin and M Cave, *Understanding Regulation*, 1999.

¹⁶ This and the following paragraphs are adapted from R Baldwin, M Cave and M Lodge 'Chapter 1, Introduction: Regulation - the field and the developing agenda' and R Baldwin, 'Chapter 12, Better regulation: the search and the struggle' in R Baldwin, M Cave and M Lodge, *The Oxford Handbook of Regulation*, 2010, pp 3-16 and 259-278.

¹⁷ This Act was a hasty piece of legislation introduced in response to a tragic accident and subsequently regarded as poorly conceived. R Baldwin in *Is Regulation Right?* (<http://www2.lse.ac.uk/researchAndExpertise/units/CARR/pdf/IsRegulationRight.pdf>), p 2, notes that this particular Act is "cited more than any other as an example of how not to go about regulating".

tendencies, articulated through the better regulation agenda, has been the spread of 'regulatory impact assessments' and 'cost-benefit analysis', both of which require a structured assessment of the likely impacts of intervention *before* the intervention occurs. I consider the importance of RIAs - particularly in the context of tobacco regulation - in section 4 below.

- 3.5 The agenda of better regulation or 'high quality regulation' was therefore an attempt to bridge these related, but also conflicting, dynamics. The Organisation for Economic and Co-operation Development (*OECD*) moved, under the influence of member state interests, towards a greater emphasis on peer-review, comparative evaluation, and the endorsement of 'high quality regulation'. From the mid-1990s onwards, the OECD sought to develop indicators of regulatory quality, and to devise strategies for improving regulatory policies, tools, and institutions. The language of better regulation, together with the endorsement of RIAs, was - by way of illustration - subsequently adopted as part of the European Union's so-called 'Lisbon Agenda' that sought to raise European industries' competitiveness.¹⁸ Indeed, debates regarding the quality of regulation have spread around the world, to countries such as Australia and Canada, as well as emerging economies such as India and Brazil (thereby embedding these countries further in a globalised regulatory discourse).
- 3.6 These trends in governmental fashions have been echoed (if not led) by changing concerns on the part of scholars of regulation. So-called 'command and control' was the traditional starting point of both regulators and regulatory scholars in the 1960s and 1970s, but by the 1980s, the deficiencies of such systems were outlined in numerous studies and calls were made for the introduction of 'less-restrictive' and 'incentive-based' controls.¹⁹ Both governmental and academic bodies of literature devoted attention to such 'alternative' modes of influence as taxation regimes and systems of information disclosure. Bodies such as the UK's Better Regulation Task Force began to commend the use of 'more imaginative' thinking about regulation and to stress the need to adopt minimalist or self-regulatory controls in the first instance.²⁰ Commentators moved on to consider the potential of more market-based strategies such as franchising and the use of trading regimes. It was a short step from that point to assess the argument for controlling not by regulating directly but by auditing the control regimes being operated within the relevant organisation.

The better regulation principles adopted by different governmental and international bodies

- 3.7 Although there was inevitably debate about how better regulation should be defined, how it should be achieved and how regulatory quality should be measured, the principles and procedures identified by the various governmental and international bodies concerned are remarkably uniform. I consider below some examples of better regulatory principles which have been cited by various bodies around the world to illustrate this point.
- 3.8 The OECD, for example, asserts that good regulation should:²¹

¹⁸ For references, see the footnotes to paragraphs 3.13 and 3.14.

¹⁹ For an influential example, see S Breyer, *Regulation and its Reform*, 1982.

²⁰ UK Better Regulation Task Force, *Principles of Good Regulation*, 2003 (<http://archive.cabinetoffice.gov.uk/brc/upload/assets/www.brc.gov.uk/principlesleaflet.pdf>).

²¹ OECD, *Guiding Principles for Regulatory Quality and Performance*, 2005 (<http://www.oecd.org/dataoecd/19/51/37318586.pdf>) (the *OECD Guiding Principles*), p 3.

- (a) serve clearly identified policy goals, and be effective in achieving those goals;
- (b) have a sound legal and empirical basis;
- (c) produce benefits that justify costs, considering the distribution of effects across society and taking economic, environmental and social effects into account;
- (d) minimise costs and market distortions;
- (e) promote innovation through market incentives and goal-based approaches;
- (f) be clear, simple and practical for users;
- (g) be consistent with other regulations and policies; and
- (h) be compatible as far as possible with competition, trade and investment-facilitating principles at domestic and international levels.

3.9 It is against this backdrop that the OECD recognises that *“a regulatory environment that is well-devised, clear, understandable and as simple as possible is key to protecting citizens’ welfare, public health and the environment”*.²²

3.10 The Australian Government also adheres to the guiding principles of good regulation set out by the OECD. Through its Office of Best Practice Regulation (**OBPR**), the Australian Government’s regulatory impact analysis requirements are intended to achieve sound analysis, informed decision-making and transparency. These analytical steps include:²³

- (a) identifying the problem or issue that gives rise to the need for action;
- (b) explaining the desired objectives;
- (c) providing a range of options (regulatory and non-regulatory, as applicable);
- (d) assessing the impact of the options;
- (e) consulting key stakeholders; and
- (f) concluding and recommending the preferred option with an implementation and review strategy.

3.11 The five principles of good regulation developed in the United Kingdom are:²⁴

- (a) proportionality: regulators should only intervene when necessary; potential solutions should be appropriate to the risk posed and costs identified and minimised;

²² *Ibid*, p 24.

²³ Australian Government, Best Practice Regulation Handbook, 2010 (<http://www.finance.gov.au/obpr/proposal/handbook/docs/Best-Practice-Regulation-Handbook.pdf>), pp 16-18.

²⁴ UK Better Regulation Executive, The Five Principles of Good Regulation (<http://www.bis.gov.uk/policies/better-regulation>).

- (b) accountability: regulators must be able to justify decisions and be subject to public scrutiny;
- (c) consistency: government rules and standards must be joined up and implemented fairly;
- (d) transparency: regulators should be open and keep regulations simple and user-friendly; and
- (e) targeting: regulation should focus on the problem and minimise side effects.

3.12 The Privy Council of Canada has also developed similar guidelines for making federal acts and regulations, which comply with the Canadian government's Cabinet Directive on Law-making, namely:²⁵

- (a) identifying the problem and defining the goals and objectives;
- (b) ensuring the proposal meets the needs of Canadians;
- (c) making proposals that contribute to the government's priorities;
- (d) rationalising the need for federal involvement;
- (e) developing adequate accountability framework, in particular for multi-stakeholder arrangements;
- (f) allowing for joint planning and collaboration; and
- (g) efficiency and affordability: proposing the most cost-effective options.

3.13 The European Commission's recommendations in this area can best be inferred from its Impact Assessment Guidelines, which set out a summary of key analytical steps required of assessors, namely:²⁶

- (a) identifying the problem;
- (b) defining the objectives;
- (c) developing main policy options;
- (d) analysing the impact of the options;

²⁵ Government of Canada Privy Council Office, Guide to Making Federal Acts and Regulations, 2nd ed., 2001 (<http://www.pco-bcp.gc.ca/docs/information/Publications/legislation/pdf-eng.pdf>), pp 72-73. The Guide also states (pp 7-8) that the sponsoring Minister proposing a new legislation has to demonstrate to the Cabinet that the legislative proposal made is the most appropriate and "*there are no other ways to achieve the policy objectives effectively*".

²⁶ See European Commission, Impact Assessment Guidelines, 15 January 2009, SEC(2009) 92 (http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_en.pdf) (the **European Commission Impact Assessment Guidelines**), which contains considerably more detail. See also European Commission, Better Regulation Simply Explained, 2006 (http://ec.europa.eu/governance/better_regulation/documents/brochure/br_brochure_en.pdf).

- (e) comparing the options; and
- (f) outlining policy monitoring and evaluation.

3.14 The European Commission - which considers better regulation as “*one of [its] core priorities*”²⁷ - has subsequently revisited this subject through the publication of its Communication on Smart Regulation.²⁸ On inspection, the main thrust of this document is to commit the Commission more firmly to assessment during the whole policy cycle and to attach more importance to assessing existing legislation and policies. As the Commission press release puts it, the resulting evidence will be put at the heart of the design of new and revised regulation.²⁹ This corresponds to the criterion of ‘incremental value’ which I consider further at paragraph 3.16(d) below.

3.15 The primary documents cited above, while providing a large degree of consistency in the goals they pursue, inevitably reflect the policy or institutional preoccupations of their authors: for example, in the case of the OECD, competition and international free trade, and in the case of the European Commission, the division of responsibility between European institutions and member states.

A proposed check-list of better regulation principles

3.16 For the purposes of the present paper, and at the risk of adding to the sets of criteria, I have found it useful to present a check-list³⁰ of the requirements of better regulation which, in my opinion, addresses the issues likely to arise in any country whenever a regulator is considering any type of regulatory intervention, including the regulation of tobacco control measures.³¹ The list, with citations to relevant sources, is as follows:

- (a) **Clarity of objectives** - the nature and scale of the problem which the regulation seeks to address must be clearly defined³² and the objectives of the regulation must be clearly stated and legitimate;³³

²⁷ *Ibid*, p 1.

²⁸ European Commission, Communication from the European Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Smart Regulation in the European Union, 2010 (http://ec.europa.eu/governance/better_regulation/documents/com_2010_0543_en.pdf) (*Smart Regulation in the European Union*).

²⁹ Smart regulation: ensuring that European laws benefit people and businesses, IP/10/1296, 8 October 2010 (<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/1296&format=HTML&aged=0&language=EN&guiLanguage=en#>).

³⁰ I note that the Office of Management and Budget (**OMB**) - the executive agency that advises the US President on the federal budget - has recently produced a check-list to assist US agencies in producing RIAs, which is cast in similar terms to the other primary documents which I consider in paragraphs 3.8-3.14 above (http://www.whitehouse.gov/sites/default/files/omb/inforeg/regpol/RIA_Checklist.pdf) (*the OMB Check-List*).

³¹ This list assumes that the regulator has a legal basis on which to act.

³² See, for example, the OECD recognises that during the process of regulatory decision-making “[t]he problem to be solved should be precisely stated, giving clear evidence of its nature and magnitude, and explaining why it has arisen (identifying the incentives of affected entities)” (OECD Reference Checklist for

- (b) **Targeting³⁴ and proportionality** - regulation should be focussed on the particular problem identified and be no more intrusive than is required and proportionate to the goal;³⁵
- (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;³⁶ impact assessments must be conducted and must be as accurate and complete as is reasonably practicable;³⁷
- (d) **Incremental value** - regulators must review and evaluate existing legislation (including whether it is being effectively enforced³⁸) and other options before regulating further;³⁹ and

Regulatory Decision-making, 1995 (the **OECD Checklist**), Question 1); European Commission Impact Assessment Guidelines, p 20.

³³ See, for example, the OECD: “*Good regulation should: (i) serve clearly identified policy goals*” (the OECD Guiding Principles, Principle 1); and the EU: “*Without clear objectives, it is impossible to evaluate the extent to which action has generated its intended effects*” (European Commission Impact Assessment Guidelines, paragraph 6).

³⁴ This also raises the need to identify measures targeted at the specific social group or type of consumers in question (an example being minors).

³⁵ UK Better Regulation Executive, The Five Principles of Good Regulation (<http://www.bis.gov.uk/policies/better-regulation>).

³⁶ See, for example, “*Good regulation should: [...] (ii) have a sound legal and empirical basis*” (OECD Guiding Principles, Principle 1); in the EU, the Commission seeks to ensure that “*policies are based on the ‘best evidence available’*” (Communication of the Commission on the collection and use of expertise of 11 December 2002 (the **2002 Communication**), p 4), and the European Commission Impact Assessment Guidelines emphasise the importance of quality evidence: “*Good quality data – facts as well as figures – are an essential part of any IA. [...] Particular attention needs to be paid to quality and credibility of data*” (European Commission Impact Assessment Guidelines, paragraph 4.1) – the Commission must give “[c]areful consideration of the evidence presented” (Inter-Institutional Agreement on Common Approach to IA, 2003, paragraph 6) and that “*sound analysis*” is undertaken (European Commission Impact Assessment Guidelines, Annex 9). Advocate General Fennelly identified the need for “*clear evidence*” in his Opinion in Joined Cases C-376/98 and C-74/99 *Germany v Parliament and Council* [2000] ECR I-8419 (**Advocate General Fennelly’s Opinion**) at paragraph 161.

³⁷ See, for example, the Inter-Institutional Agreement on Common Approach to IA, 2003, paragraph 5, that it is “*essential*” that “*the assessment of the impacts of initiatives and substantive amendments is rigorous and comprehensive, and is based on accurate, objective and complete information*”. Similarly, the UK Better Regulation Executive has stated that “*Impact Assessments are generally required for all UK Government interventions of a regulatory nature that affect the private sector, the third sector and public services. They apply regardless of whether the regulation originates from a domestic or international source*” (UK Better Regulation Executive, Impact Assessment Guidance, 2010 (<http://www.berr.gov.uk/assets/biscore/better-regulation/docs/10-898-impact-assessment-guidance.pdf>) (**BRE Impact Assessment Guidance**)).

³⁸ See, for example, European Commission Impact Assessment Guidelines, p 30: “*where legislation is already in place, better enforcement and implementation should always be considered, perhaps with improved guidance*”.

³⁹ See, for example, OECD, The OECD Report on Regulatory Reform: Synthesis, 1997; OECD Checklist, Questions 1 and 4; OECD Guiding Principles, Principle 1; Mandelkern Group on Better Regulation, Final Report, 2001 (the **Mandelkern Report**), pp 12 and 14.

- (e) **Enforceability** - regulation must be capable of being complied with and enforced effectively.⁴⁰

3.17 The discussion which follows will refer back to these considerations.

4. THE IMPORTANCE OF REGULATORY IMPACT ASSESSMENT.

4.1 The RIA is, for the reasons which I consider in this section, a powerful force in aiding the implementation of the better regulation principles which I described in section 3. In the context of regulating tobacco products, an effective RIA should ensure that the regulatory process is a thorough one, and one which is given the same depth of analysis and collection of evidence as applies in other areas.

4.2 Based on my experience regarding the design of regulatory policies to achieve economic, and also social, objectives, there are two specific issues which are of particular relevance to the regulation of tobacco products. These two issues, which I consider below, mean that a number of important consequences flow from the better regulation analysis contained within the previous section.

4.3 The first issue is that I understand (albeit acknowledging that I am not an expert in the underlying technical disciplines) that there is not a consensus on the actual impact or likely impact of the Proposals.

4.4 The second issue stems from the recognition that tobacco is a product with serious health risks. Thus debate surrounding the regulation of tobacco products is inevitably emotive and - in the absence of better regulatory safeguards - potentially susceptible to the type of insufficiently considered regulatory response that I referred to at paragraph 3.4 above (possibly adopted even in the absence of supportive evidence as to the impact of proposed regulatory interventions).

4.5 It is in this context, and from my experience of impact assessment processes, that I evaluate below the importance of the RIA. For the reasons which I consider more fully in the text that follows, RIA is - in my view - a key tool in addressing the two issues raised above.

The nature of RIA

4.6 RIA is a systematic procedure, often used in the pre-legislative scrutiny of legislation, to predict and measure the impact of regulation on stakeholders, economic and social sectors, and the environment, often using sophisticated empirical techniques.⁴¹ As the European Court of Auditors has noted, the RIA procedure should be an open process since “*public*

⁴⁰ See, for example, the World Bank, *Doing Business in 2004: Understanding Regulation, 2004*; “*Review of European legislation should include specific consideration of its administrability and enforceability*” (the Mandelkern Report, p 72); the OECD: “*Realistic assessment of expected compliance rates, based on available compliance and enforcement strategies, may suggest that one policy instrument is more attractive than another that appears more effective on paper, but is likely to be more difficult to implement*” (OECD Checklist, Question 10); and the UK Treasury’s Hampton Review, *Reducing administrative burdens: effective inspection and enforcement, 2005, Principal Recommendations*.

⁴¹ Chapter 8 (in particular paragraph 8.2 of that chapter) of the European Commission Impact Assessment Guidelines provides an illustration of the type of impacts that an RIA may be expected to consider.

*scrutiny is an effective verification mechanism to ensure that [impact assessments] address the most relevant issues, include all feasible policy options and provide a balanced view”.*⁴²

- 4.7 The expected effects analysed via RIA may cover administrative burdens or basic compliance costs, or more complex types of costs and benefits, including environmental benefits, health benefits, distributional effects and the impact on trade and competition. The scope of economic activities covered by RIA ranges, according to circumstances, from the output of a number of firms to whole economic sectors, and to the economy or society as a whole. Generally, as Radaelli and de Francesco have noted:⁴³

“[The] sophistication and analytic breadth [of RIAs] vary, depending on the issues at stake and the resources available - the degree of sophistication should be proportional to the salience and expected effects of the regulation”.

- 4.8 The UK Cabinet Office⁴⁴ document A Quick Guide To Regulatory Impact Assessment (2003) (the **UK Cabinet Office Guidance**)⁴⁵ amplifies the need for an RIA, and what it should address, in the following terms:

“The principle of RIA is evidence-based policy making. An RIA must set out the risk or problem to be addressed and the options available - including ‘do nothing’ and any non-regulatory options, such as Codes of Practice, industry standards or information campaigns. It must also set out the likely costs and benefits for each option. A good RIA will answer the question “Is this the best way of achieving the objective?””

- 4.9 RIAs are thus intended to inform decision-making, not to determine decisions or to substitute for political accountability. The expectation is that the RIA process will “enable policy solutions to be created in a way that minimises unnecessary or undesirable impacts or burdens whilst maximising the positive impacts and hence achieving the policy objectives in an effective way”.⁴⁶ RIAs seek to achieve this by encouraging better, more rational, regulation through, amongst other things:

- (a) clearly identifying what the problem is and clarifying objectives;
- (b) involving and engaging all affected stakeholders through consultation;⁴⁷

⁴² European Court of Auditors, Special Report No 3/2010 – Impact assessments in the EU institutions: do they support decision-making? (the **European Court of Auditors Report**) (<http://eca.europa.eu/portal/pls/portal/docs/1/5372733.PDF>), p 29.

⁴³ C Radaelli and F de Francesco, ‘Regulatory Impact Assessment’ in R Baldwin, M Cave and M Lodge (eds.), *The Oxford Handbook of Regulation*, 2010, pp 279-280. See also the European Commission Impact Assessment Guidelines, p 14, which states that, in defining the right level of analysis for the impact assessment, it is necessary to answer a number of questions, including “how significant are the likely impacts?” and “how politically important is the initiative?”.

⁴⁴ The body which coordinates policy and strategy across UK government departments, see further: <http://www.cabinetoffice.gov.uk/>.

⁴⁵ http://www.inmetro.gov.br/qualidade/comites/docGovern0_guide.pdf.

⁴⁶ Mandelkern Report, p 19.

⁴⁷ See, for example, the European Commission Impact Assessment Guidelines, p 19, which states that, for the purposes of Commission impact assessment, consulting interested parties “is an obligation for every IA

- (c) considering how compliance will be achieved (in the UK Cabinet Office document referred to at 4.8 above, this is described as “*enforcement arrangements for securing compliance with each of the proposed options and your plans for guidance*”);
- (d) considering the criteria to be used for monitoring and evaluating the regulatory activity at issue;
- (e) considering alternatives (including alternatives to the introduction of the regulatory measure being proposed, including: (i) what the UK Cabinet Office - in the quote set out above - refers to as the ‘do nothing’ option; (ii) better enforcing existing regulation; (iii) any non-regulatory options; and (iv) the availability of alternative regulatory solutions with the potential to minimise or remove the risk of negative, unintended consequences) and demanding that different ways of reaching regulatory objectives should be compared, thereby increasing transparency;⁴⁸ and
- (f) identifying the most cost effective way of achieving the defined objectives (what the UK Cabinet Office - in the quote set out above - refers to as “*the likely costs and benefits for each option*”). This is important to ensure that regulation is both targeted and proportionate, something I discussed further at 3.16(b) above.

4.10 Although RIA is often used prospectively to estimate the impact of proposed regulation, it can also be used to examine the effects of regulations that are currently in force, for example with the aim of eliminating some burdensome features of existing regulations or to choose the most effective way to simplify regulation. The use of RIAs as part of an ex-post evaluation of regulation is consistent with the principle of better regulation which I identified at paragraph 3.16(d) of my report, namely that regulators must review and evaluate existing legislation and other options before regulating further.⁴⁹

and it must follow the Commission’s minimum standards” and is an “essential tool for producing high quality and credible policy proposals”. See also European Commission, The Working Methods of the Commission 2010-2014, C(2010) 1100 (http://ec.europa.eu/commission_2010-2014/president/news/documents/pdf/c2010_1100_en.pdf), p 10: “Consultation is also an obligation for every impact assessment: stakeholders should be able to comment on a clear problem definition, an analysis of subsidiarity, and a clear description of the possible options”.

⁴⁸ UK Cabinet Office Guidance. See also the European Court of Auditors Report, p 46: “*Transparency lends credibility, and the Commission’s approach to impact assessment is strongest where it provides such transparency*”.

⁴⁹ This point has recently been reinforced in the EU by the European Court of Auditors Report. Under a heading entitled “*Ex post evaluations of existing policies and programmes are not carried out systematically across all legislative areas*”, it is stated that: “[a] *public intervention (and its actual impact) should be assessed through ongoing monitoring and ex post evaluation to improve further development of interventions. To enable learning and feedback for future initiatives, ex post evaluations would need to collect relevant information on compliance with legislation and the effectiveness of the rules as compared with the envisaged results initially set out in the [RIA]*” (European Court of Auditors Report, p 42).

Global recognition of the importance of RIA

- 4.11 RIA has spread throughout the globe,⁵⁰ and is seen as a key tool of regulatory improvement in the United Kingdom and many other countries, including other OECD countries.⁵¹ The OECD's flagship report on regulatory reform⁵² suggested that better regulation should be pursued through the adoption, at the heart of government, of regulatory improvement as a policy; the establishing of institutions dedicated to regulatory improvement; and, significantly, the application of a series of regulatory improvement tools, including RIAs. In Australia too, for example, the RIA is considered an essential part of the regulatory process and must be submitted by the entity responsible for the regulatory proposal to the Office of Best Practice Regulation for review.⁵³ The European Commission has also hailed RIA as a key tool for transparent and accountable governance in multilevel political systems.⁵⁴
- 4.12 A further indication of the increased international importance of RIA in the regulatory process is the European Commission's recently announced commitment to upgrade its own impact assessment system by strengthening the role of the independent Impact Assessment Board (**IAB**). In principle, a positive opinion of the IAB (whose function it is to provide an impartial analysis of the content and conclusions of impact assessments) is now required before a proposal can be put forward for Commission decision.⁵⁵ This commitment is a feature of the European Commission's drive to gear up its better regulation agenda towards "*smart regulation*", with the stated objective of producing legislation "*of the highest quality possible*".⁵⁶ In my opinion, this is not a development only of relevance to the EU and its member states; it reinforces the need for a thorough RIA process wherever regulation is being considered, whether in a tobacco-related or other context.

⁵⁰ See further, P Ladegaard, 'Improving Business Environments through Regulatory Impact Analysis – Opportunities and Challenges for Developing Countries' in International Conference on Reforming the Business Environment, 2005 (<http://www.businessenvironment.org/dyn/be/docs/80/Session3.4LadegaardDoc.pdf>); S Jacobs, Current Trends in Regulatory Impact Analysis: The Challenges of Mainstreaming RIA into Policy-Making, 2006; C Kirkpatrick and D Parker, Regulatory Impact Assessment: Towards Better Regulation?, 2007; C Kirkpatrick, D Parker and Y Zhang, 'Regulatory Impact Assessment in Developing and Transition Economies: A Survey of Current Practice' in Public Money and Management, 2004, 24(5): 291-6; S Weatherill, Better Regulation, 2007; J Wiener, 'Better Regulation in Europe' in Current Legal Problems, 2006, 59: pp 447-518.

⁵¹ See for example UK Cabinet Office Guidance; UK Better Regulation Executive, The Tools to Deliver Better Regulation, 2006, p 4.

⁵² OECD, The OECD Report on Regulatory Reform: Synthesis, 1997. See also European Commission Impact Assessment Guidelines, p 4: "*IA work is a key element in the development of Commission proposals*".

⁵³ Australian Government, Best Practice Regulation Handbook, 2010 p 7: The RIA ensures the OBPR's decision "*is informed by a balanced assessment of the best available information*".

⁵⁴ European Commission, European Governance: A White Paper, COM(2001) 428 final, 2001 (http://eur-lex.europa.eu/LexUriServ/site/en/com/2001/com2001_0428en01.pdf).

⁵⁵ Smart Regulation in the European Union, p 6.

⁵⁶ *Ibid*, p 3.

RIA and the regulation of tobacco products

4.13 In relation to tobacco control measures of the kind considered more fully below in sections 8 and 9, the implementation of an RIA should, in my view and in light of the previous discussion, aspire to take account of the following factors:

- (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.

4.14 In the remaining sections of this report I develop some of the themes which I have explored in this section (in particular, in paragraphs 4.9 and 4.13) which are themselves practical articulations of the better regulation principles developed in section 3. More particularly, I explore, based on my extensive experience of regulatory impact assessment, what the practical implications of certain of these themes are for regulators in any jurisdiction when regulating tobacco products and, in particular when considering the introduction of measures such as the Proposals. In this respect the next sections of this report focus upon the importance of the regulator doing the following:

- (a) **Identifying the problem and goal(s)** (section 5) - clearly defining the problem and goal(s) of government policy and legislation;
- (b) **Assessing the evidence base** (section 6) - carefully assessing the evidence base underlying any proposed regulatory intervention (which is particularly critical where a novel regulatory intervention is being considered for the first time);
- (c) **Evaluating implementation and enforcement** (section 7) - having regard both to whether existing regulation has been effectively implemented and is being

effectively enforced, and whether the regulation being proposed is capable of being complied with;

- (d) **Assessing the suitability of the Proposals** (section 8) - considering the approach any regulator must take when assessing the Proposals and considering their better regulation implications; and
- (e) **Assessing alternative measures** (section 9) - considering possible alternative means of achieving the objectives that the Proposals are aimed at.

4.15 I now address each of the above in turn.

5. BETTER REGULATION PRINCIPLES TO BE APPLIED TO TOBACCO PRODUCTS - PROBLEM, POLICY AND OBJECTIVE DEFINITION.

5.1 Based on my experience regarding the design of regulatory policy, the criteria set out at paragraphs 3.16(a) and 4.9(a) of clarity of objectives and of targeting suggest that: first the problem definition process should encapsulate why action is required; secondly, a public policy goal of regulation has to be clearly stated and legitimate; and thirdly, there needs to be a rational connection between the goal(s) and the effects of the measure over the chosen time period.⁵⁷

5.2 This rather obvious view is, as noted above, confirmed by the OECD, whose Guiding Principles recognise that *“good regulation should serve ... clearly identified policy goals and be effective in achieving those goals”*.⁵⁸ A UK Government report on better regulation notes that it is important when devising regulation *“to understand the problem and the steps likely to ensure additional behaviour change”*.⁵⁹ The European Commission also recognises that one of the three ‘general criteria’ for evaluating policy options at the point of impact assessment is *“effectiveness”*, which it defines as *“the extent to which options achieve the objectives of the proposal”*.⁶⁰

Defining the problem

5.3 As indicated in section 3 above, appropriate analysis of the problem which any proposed regulation is intended to solve is a well established principle of better regulation and, as I noted in section 4, should find practical articulation by typically being a feature at the very heart of a good RIA. Indeed, the European Commission’s Impact Assessment Guidelines - as well as many other statements of better regulation principles (including, for example the

⁵⁷ See footnote 36.

⁵⁸ OECD Guiding Principles, p 5.

⁵⁹ UK Department for Business, Innovation and Skills (**BIS**), Better Regulation, Better Benefits: Getting the Balance Right, 2009 (<http://www.bis.gov.uk/files/file53252.pdf>) (the **BIS Report**), p 23.

⁶⁰ European Commission Impact Assessment Guidelines, p 48. Indeed the European Commission suggests that where, as part of the impact assessment, the regulator has identified a number of options capable of meeting the stated objective, it is necessary to *“start by ranking [...] [each] option on the basis of the effectiveness criteria and so identify the option that scores best on effectiveness i.e. meets the defined objectives best”* (European Commission Impact Assessment Guidelines, p 48).

OECD Reference Checklist for Regulatory Decision-making⁶¹) - recognise that “a good definition of the problem and a clear understanding of what causes it are preconditions for setting objectives and identifying options to address the problem”.⁶²

- 5.4 To address problem definition properly means that the reasons behind any proposal and the results that it is intended to reach should be clearly identified and expressed. However, different people or groups can define the problem differently and/or identify different factors which should explain the existence of the problem.
- 5.5 A first step for any regulator, therefore, should be to gather and examine existing problem “definitions”. This requires some choices about which “definitions” should be taken into account and how. In this respect, a research paper commissioned in 2004 by the EU Directors of Better Regulation Group made a number of recommendations:⁶³

“1) Appropriate problem definition: The problem that the proposal is intended to ‘solve’ should be clearly identified and explained. It should be quantified wherever possible (for example, how many people are affected?). The magnitude of the problem should be quantified wherever possible. The risks implied if the problem is not eliminated should also be taken into account.

2) Explanation of the problem: Why has the problem arisen? The RIA should identify the market (or Government) failure. In addition, it should contain a risk assessment, identifying the situation that is causing harm and probability that the situation will occur”.

- 5.6 Once a problem which needs to be addressed has been identified, it falls upon the regulator to state the objectives of any proposed regulatory solution, and these objectives must be both clearly stated and legitimate. I consider this below.

Defining the objectives of tobacco regulation

- 5.7 In practice, governments often and quite legitimately express the objectives of their policies (even if not their specific legislative proposals) in wide terms. In the context of tobacco regulation, an example comes from Australia, here the Australian Government’s National Preventative Health Strategy, ‘Australia: the Healthiest Country by 2020’ (2009), which states:

“The case for action on tobacco is clear. Since 1950, when the dangers of smoking were recognised, almost one million Australians have died because they smoked. Trends in recent years have been encouraging, but there is no room for complacency while the death toll from tobacco continues, thousands of young people each year start smoking, non-smokers are exposed to second-hand smoke, disadvantaged

⁶¹ OECD Checklist, p 1: “The problem to be solved should be precisely stated, giving evidence of its nature and magnitude, and explaining why it has arisen [...]”.

⁶² European Commission Impact Assessment Guidelines, p 21. On problem identification generally, see section 5 of the same guidelines: ‘What is the Problem?’.

⁶³ A Comparative Analysis of Regulatory Impact Assessment in Ten EU Countries: A report prepared for the EU Directors of Better Regulation Group, 2004 (http://www.betterregulation.ie/eng/Publications/Report_on_RIA_in_the_EUa.pdf), p 13.

*groups are disproportionately affected, the overall cost of smoking to the economy is more than [AUS]\$30 billion each year, and tobacco companies maintain efforts to promote sales of their lethal product”.*⁶⁴

5.8 Whilst it is legitimate for the overall policy to be expressed in wide terms, the ‘clarity of objectives’ better regulation principle I refer to at paragraph 3.16(a) above requires that, in addition, there should be specific, clearly stated, and legitimate objectives to which particular measures should be targeted.

5.9 Taking another example, again by way of illustration, according to the Commission’s September 2010 public consultation document cited at the outset of this paper (namely at paragraph 1.6), the current EU Tobacco Products Directive has the objectives of facilitating the functioning of the internal market in the tobacco products sector while ensuring a high level of protection to public health.⁶⁵ The preamble to the Directive itself states:

“(4) In accordance with Article 95(3) of the Treaty, a high level of protection in terms of health, safety, environmental protection and consumer protection should be taken as a basis, regard being had, in particular, to any new developments based on scientific facts; in view of the particularly harmful effects of tobacco, health protection should be given priority in this context”.

5.10 In my opinion, this is a vague and unhelpful specification of objectives. Fortunately, the specification of the goals of more narrowly defined pieces of legislation is generally clearer in their objectives.

5.11 To illustrate this point further I consider a couple of specific examples of objectives cited by regulators in the United Kingdom in respect of certain of the Proposals, and briefly consider the extent to which - in my view - they satisfy the requirement of better regulation to spell out specific, clearly stated, and legitimate objectives.

Scotland

5.12 I am aware of the consultation process in Scotland in respect of the Tobacco and Primary Medical Services (Scotland) Act 2010, which I understand will introduce, among other measures, a ban on the display of tobacco products in retail outlets.

5.13 On its publication, the Scottish Parliament’s Health and Sport Committee sought views from stakeholders in respect of the Bill and its supporting documents. Each of the supporting documents contained a number of comments from which it is possible to infer a number of public policy objectives purporting to underpin the Bill, including:

⁶⁴ Australian Government’s National Preventative Health Taskforce, Australia: The healthiest country by 2020: National Preventative Health Strategy – the roadmap for action, 2009, p 170, footnotes omitted ([http://www.preventativehealth.org.au/internet/preventativehealth/publishing.nsf/Content/nphs-roadmap/\\$File/nphs-roadmap.pdf](http://www.preventativehealth.org.au/internet/preventativehealth/publishing.nsf/Content/nphs-roadmap/$File/nphs-roadmap.pdf)).

⁶⁵ See footnote 3.

- (a) “[t]o reduce the attractiveness, availability and consumption of tobacco products among older children and adolescents under the age of 18 leading to a reduction in smoking prevalence”;⁶⁶
- (b) a suggestion that the Scottish Government’s “particular focus” is to reduce youth smoking initiation (“[...] preventing children and young people starting to smoke in the first place”);⁶⁷ and
- (c) the “intended outcome” of a display ban is identified as “reduc[ing] the number of under 18 year olds who take up smoking due to awareness of tobacco products from display [...]”.⁶⁸

5.14 Following the passage of the Bill by the Scottish Parliament, the Scottish Government published a consultation in respect of draft regulations under the Act. In respect of the draft Tobacco and Primary Medical Services (Scotland) Act 2010 (Display of Tobacco and Prices) Regulations 2010, the Scottish Government was more explicit in stating the public policy objective underpinning the introduction of a display ban: “the policy aim of these regulations is to protect children and young people under 18 from the promotion of tobacco through the display of tobacco and smoking related products in places where tobacco products are for sale, whilst minimising the impact on retailers”.⁶⁹

5.15 In my opinion and based on my experience of assessing the design of regulatory policies to achieve economic, and also social, objectives, the objectives have been specified in enough detail here such that it is at least possible to permit the process of collecting evidence and performing an RIA. The final passage quoted also refers explicitly to the two objectives of stopping minors from smoking and minimising the impacts on retailers. These may be conflicting goals, and an appropriately conducted RIA should bring this out.

England and Wales

5.16 Another example of relevance to tobacco regulation also demonstrates that official documents betray confusion over goals. This has been evidenced in the UK where the Department of Health, for example, states in its ‘Consultation on the future of tobacco control’ (2008) that there are “several reasons” for prohibiting point of sale display, including:

- (a) protecting children and young people from the promotion of tobacco;
- (b) providing an environment that supports smokers who are trying to quit;

⁶⁶ Tobacco Provisions to be contained in the Health (Scotland) Bill (<http://www.scotland.gov.uk/Publications/2009/02/27120518/4>), paragraph 2.1.

⁶⁷ *Ibid*, paragraph 2.13.

⁶⁸ *Ibid*, paragraph 8.12.

⁶⁹ See The Tobacco and Primary Medical Services (Scotland) Act 2010: A Consultation on Tobacco Draft Regulations (<http://www.scotland.gov.uk/Publications/2010/04/27151930/7>).

- (c) 'denormalising' tobacco use;⁷⁰ and
 - (d) ensuring that health messages about the dangers of tobacco use are not undermined.
- 5.17 The RIA which is produced in that consultation paper goes further and states that "*the primary objective [of restrictions on, or prohibition of, the display of tobacco at the point of sale] is to reduce smoking take up in under 18s*".⁷¹
- 5.18 In the same consultation document, the UK Department of Health sought views on whether plain packaging, as defined in paragraph 3.64 of that document, has merit as an initiative "*to reduce smoking uptake by young people*". The reduction of smoking uptake by 'young people' was the only stated public policy objective of plain packaging.
- 5.19 This is potentially important because, as noted above, and in conformity with at least some of these texts to which I am now referring, I make a sharp distinction between the objectives of policy relating to adults and those relating to minors. In the latter case, a paternalist policy may be deemed appropriate by the regulator in light of better regulation principles. In the case of adults, it is not and different solutions may be needed (albeit effective measures aimed at preventing youth initiation can be expected to have a longer term impact on adult smoking prevalence on the basis that I understand a high proportion of adult smokers start smoking as minors). It is therefore appropriate to distinguish between regulations affecting the sale of tobacco which proscribe certain forms of conduct, and regulation which enhances the availability of information.
- 5.20 The mandatory introduction of health warnings on cigarettes (which first occurred in the US in 1966⁷²) falls into the category of what I call 'enhancing' information remedies, which add to or emphasise the stock of information already available. Other measures such as prohibiting the display of tobacco products at point of sale and plain packaging - although they deal with information - fall into what I call the 'proscriptive' category. Their implementation must as a practical matter affect purchases both by adults and by minors. This may complicate the assessment process and, in keeping with the above noted principle of targeting and proportionality and views I discuss below,⁷³ it may lead to a preference for alternative interventions to the extent that they are available (something I return to in sections 8 and 9 below).
- 5.21 The fundamental point, therefore, is that better regulation norms require that the decision by the regulator as to how to regulate - particularly when considering measures such as the

⁷⁰ It is unclear to me what precisely is intended by this term. It is not a term defined in the Oxford English Dictionary.

⁷¹ UK Department of Health, Consultation on the future of tobacco control, 2008 (http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_085651.pdf) (the *DoH Consultation*), p 68.

⁷² The US Cigarette Labeling and Advertising Act was passed on 27 July 1965. It required that all cigarette packets contain the following warning: "*Caution – Cigarette smoking may be hazardous to your health*". It took effect in 1966.

⁷³ I refer at paragraph 6.11 below to a remark made by a former Advocate General of the European Court of Justice on the necessity to "*supply coherent evidence that the measure will be effective in achieving the public interest objective invoked and that less restrictive measures would not have been equally effective*".

Proposals - should always be developed by reference to clear objectives. As I have indicated above, there has been a tendency to date for regulators when considering measures such as the Proposals, to regulate by reference to objectives which are ambiguous or even confusing.⁷⁴ In these circumstances it becomes very difficult (if not impossible) later meaningfully to assess whether the regulatory intervention has been successful in achieving its objective(s).

6. BETTER REGULATION PRINCIPLES TO BE APPLIED TO TOBACCO PRODUCTS - THE EVIDENCE UNDERLYING IMPACT ASSESSMENT.

6.1 As I noted in section 4, the need for any regulator to perform a detailed and thorough evidence-based RIA before introducing new regulation is now fully recognised.⁷⁵ Also recognised is the need - as indicated both at paragraphs 3.16(c) and 4.13(b) above - for that impact assessment to be supported by the best available and credible evidence that the measure proposed will be effective in achieving a legitimate, stated goal. Clear and up-to-date evidence is necessary to support regulatory intervention.

6.2 In the case of the regulation of the sale of tobacco products, the evidence frequently cited is subject to a number of considerations relevant to the preparer of an RIA, which I consider more particularly in this section. I do so in order to emphasise the importance from a better regulation perspective of a regulator approaching the relevant evidence base in the right way, but I do not comment on the actual reliability of the specific evidence presented in respect of any of the Proposals. This latter evaluation, particularly at the point of preparing an RIA, should be conducted by those with expertise in the relevant scientific or technical discipline.

Particular considerations that apply to ‘first mover’ scenarios where there is no direct evidence of effectiveness

6.3 My understanding is that, while there is an historical statistical base on the prevalence and levels of consumption of tobacco products in many markets, there are relatively few statistical analyses of the impact of the Proposals.⁷⁶ This applies particularly strongly to a regulatory option like plain packaging, which - as the Commission’s RAND Europe Report states⁷⁷ - has not been implemented anywhere. This ‘first mover’ scenario raises a number of better regulation-related considerations for a regulator.

⁷⁴ The English and Welsh objectives at paragraph 5.16 illustrate such confusion.

⁷⁵ The EU, for example, has recognised that “*impact assessments are now essential parts of the policy making process*” (Smart Regulation in the European Union, p 2) and the UK Better Regulation Executive has stated that “*Impact Assessments are generally required for all UK Government interventions of a regulatory nature that affect the private sector, the third sector and public services. They apply regardless of whether the regulation originates from a domestic or international source*” (BRE Impact Assessment Guidance, p 3).

⁷⁶ For example, in respect of plain packaging, the UK Department of Health notes in the DoH Consultation,(p 40) that: “*The Department of Health is not aware of any precedent of legislation in any jurisdiction requiring the plain packaging of tobacco [...]. As there are no jurisdictions where plain packaging of tobacco products is required, the research evidence into this initiative is speculative, relying on asking people what they might do in a certain situation*”.

⁷⁷ RAND Europe, Assessing the Impacts of Revising the Tobacco Products Directive, 2010 (http://ec.europa.eu/health/tobacco/docs/tobacco_ia_rand_en.pdf) (the **RAND Europe Report**), p 131:

- 6.4 In my experience, statistical evidence of a proposed measure’s actual effectiveness in changing behaviour will generally be sought by a regulator as part of an assessment of the evidence base. In the circumstances of the ‘first mover’, however, such statistical evidence will not be available. For example, there can be no direct evidence of whether plain packaging does change smoking behaviour when no regulator has mandated plain packaging.
- 6.5 As a matter of better regulation principles, this absence of direct evidence does not remove the need, generally, for impact assessment to be supported by other credible evidence that the measure proposed will be effective in achieving a legitimate, stated goal.⁷⁸ It may, however, make it necessary to examine other *forms* of evidence that might not ordinarily be relied upon. For example, the regulator or the preparer of the RIA will require reliable and meaningful predictive evidence as to the likely effect of any such remedy on the behaviour of the individuals in question (which may be a specific social group or type of consumer), to justify the adoption of such a measure.⁷⁹
- 6.6 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.⁸⁰ 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.

Considerations that apply when considering any evidence

- 6.7 Even where some evidence is available regarding the Proposals, much of it is prepared by individuals or organisations which are arguably *parti pris*. One manifestation of this is that the RAND Europe Report (referred to above), when it cites certain evidence, adds: “*any evidence from researchers funded by the tobacco industry should be carefully considered given the industry’s history of interfering with tobacco control policy and of funding research*”

“Given that no country has implemented plain packaging to date, no observed data currently exist on the impact of plain packaging on consumer behaviour”.

⁷⁸ Indeed, the European Court of Auditors, among others, has recognised that “*in those cases where quantification and monetisation [of impacts] is difficult, a robust analysis of qualitative aspects can help to compare alternative options*” (European Court of Auditors Report) p 39.

⁷⁹ As discussed further below, Advocate General Fennelly identified the need for the legislator (and presumably also a regulator) to “*supply coherent evidence that the [proposed] measure will be effective in achieving the public interest objective invoked*” (Advocate General Fennelly’s Opinion, paragraph 159). The European Commission also recognises that an early step in the impact assessment process is the identification of “*possible options that are likely to be able to achieve the proposed objectives*” (European Commission Impact Assessment Guidelines, p 30).

⁸⁰ The OMB Check-List, for example, asks of the RIA preparer whether “*the information in the RIA [is] based on the best reasonably obtainable scientific, technical and economic information, and is it presented in an accurate, clear, complete and unbiased manner?*”, p 1.

to counter independent research on the health impacts of tobacco".⁸¹ But this cuts both ways. I would be surprised if evidence submitted from a body such as the European Network for Smoking Prevention, which I understand is funded by the European Commission, came up with conclusions which cast doubt on, for example, the benefits of plain packaging of cigarettes.⁸²

- 6.8 What can be done in such circumstances? One recourse is to rely on the peer review process of academic journals. As is alleged to have happened in climate science,⁸³ this process may be threatened in circumstances of extreme animosity or controversy, but it may still act as a bulwark against the publication of poorly reasoned or evidenced orthodox studies (which opponents will easily expose). But it may exclude heterodox work, and result in a publication bias against those opposing the majority or 'officially endorsed' view. In the circumstances, the best policy may be - in my view - for the regulator to review all results carefully, and to review them particularly carefully where the research is commissioned by an organisation with a vested interest in one direction or another.
- 6.9 Where the existing evidence base is non-existent or poor, there is a case for the decision taker to commission research⁸⁴ which satisfies the necessary objective standard of proof. In these circumstances, it would normally be appropriate for the regulator to await that evidence before implementing a measure.⁸⁵ Once that evidence base has been prepared, it would be consistent with the better regulation principle of transparency (see for example paragraph 3.11(d) above) for it to be made publicly available so that it can be reviewed and considered by others.⁸⁶

Considerations as to the standard of proof

- 6.10 A further issue concerns what that standard of proof actually is. In simple terms, to what extent must a regulator be able to show that a proposal will meet its intended goal?
- 6.11 The standard may vary in different jurisdictions, but as a matter of core principles, a UK Government report on better regulation notes that it is important when devising regulation *"to understand the problem and the steps likely to ensure additional behaviour change"* (emphasis added).⁸⁷ A similar inference can be drawn from the European Commission's

⁸¹ RAND Europe Report, p 195. It should be recalled that the present paper has been prepared on behalf of a tobacco products manufacturer.

⁸² And in fact they do not: see European Network for Smoking Prevention, Plain tobacco product packaging as a means to protect young people and adult consumers, 2010 (http://www.ensp.org/sites/default/files/ENSP_plain_packaging_20091202_EN.pdf).

⁸³ In November 2009, for example, a number of allegations were made that certain climatologists colluded in manipulating data to support the widely held view that climate change is real, and is being largely caused by the actions of mankind.

⁸⁴ As noted above, the research must be impartial and credible.

⁸⁵ The conditions for the operation of the precautionary principle, justifying intervention without a proper evidence base, do not appear to me to be satisfied for the Proposals.

⁸⁶ The OMB Check-List, for example, asks the RIA preparer whether *"the data, sources and methods used in the RIA [are] provided to the public on the internet so that a qualified person can reproduce the analysis"* (OMB Check-List, p 1).

⁸⁷ BIS Report, p 23. As part of this exercise, the regulator should also clearly state precisely what behaviour it is that he is seeking to change.

recognition that an important step in the impact assessment process is “*to establish which options and delivery mechanisms are most likely to achieve [the defined] objectives*” (emphasis added).⁸⁸ We are also assisted here by an opinion of Advocate General Fennelly delivered in connection with a challenge to the validity of the EU’s Tobacco Advertising Directive.⁸⁹ The context is thus one of a restriction of commercial speech. The Advocate General observes that:

- (a) a “community legislator should be obliged to satisfy the Court that it had reasonable grounds for adopting the measure in question in the public interest. In concrete terms it should supply coherent evidence that the measure will be effective in achieving the public interest objective invoked ... and that less strict restrictive measures would not have been equally effective” (paragraph 159);
- (b) “the community [legislator] should not be prevented from acting in the public interest simply because justification of its actions necessarily depends, not on hard scientific studies but on evidence of a social scientific character, which predicts, on the basis of past behaviour, the future response of consumers to changes in their level of exposure to promotional material” (paragraph 160);
- (c) a legislator can act with the support of “reputable specialist studies in the field”, even if other apparently reputable studies reached a contrary conclusion (paragraph 160);
- (d) “evidentiary requirements may be less strict where public health is at stake” (paragraph 161); and
- (e) “[...] it would be ... insufficiently respectful of freedom of expression to go beyond [the standard set out in (b) above] and to permit the legislator to restrict the exercise of that right without any clear evidence that such a restriction is likely to result in changes in behaviour which, in turn, were likely to benefit public health” (paragraph 161).

6.12 Putting these propositions together, it appears to be suggested by the Advocate General that in the case of tobacco consumption (which has a major public health dimension), limitations of commercial speech are legitimate in certain circumstances, and do not require unanimous expert support;⁹⁰ but the legislator (and presumably the regulator too) must have clear evidence that the measure is likely to result in changes in behaviour, and must be satisfied that less restrictive measures would be not have been equally effective (a theme which I consider further at sections 8 and 9 below).

6.13 In summary therefore, 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. Where the latter is absent, as I understand is the case in relation to plain packaging, it would be

⁸⁸ European Commission Impact Assessment Guidelines, p 29.

⁸⁹ Advocate General Fennelly’s Opinion.

⁹⁰ Albeit such a measure would still, as indicated at paragraph 3.16(c), require a reliable evidence base.

consistent with better regulation principles for the regulator to commission such evidence before implementing such a measure.

7. BETTER REGULATION PRINCIPLES TO BE APPLIED TO TOBACCO PRODUCTS – IMPLEMENTATION AND ENFORCEMENT.

Are existing measures being implemented and enforced effectively?

- 7.1 As I have indicated previously in this report (see, in particular paragraphs 3.16(d) and 4.9(e) (above)) in my experience, it is important for a regulator when considering further regulatory intervention to consider whether existing regulations are being effectively implemented and enforced. If they are not, then the regulator should consider whether doing so would obviate the need for new measures. Acting in this way helps to avoid what Robert Baldwin and I describe in our 1999 book as the undesirable situation of “*regulatory ratchet*” whereby “*regulatory rules tend to grow rather than recede because revisions of regulations are infrequent; work on new rules tends to drive out attention to old ones; and failure to carry out pruning leads the thickets of rules to grow ever more dense*”.⁹¹ It is also consistent with the view expressed in that same book that “*ill-enforcement can undermine the most sophisticated designs of regulation*”⁹².
- 7.2 There is a further important element of the analysis relating to implementation, in particular the criterion of enforceability noted in section 3 above. Many RIAs implicitly assume that implementation of the measures will be perfect. In practice it is likely to be difficult and partial. There is thus merit in taking proper account of implementation failures (in other words, acknowledging that virtually no measure can be 100% effective). This might occur in relation to the regulatory option of ensuring that those under a specified age do not get access to cigarette vending machines. Various technical means exist to prevent this, costing different amounts to install. Yet it can be assumed that none of them is 100% effective (because, for example, minors may still be able to obtain tobacco products from vending machines by means of proxy purchase by an adult). In fact the UK Department of Health’s RIA of this regulatory option (cited previously at paragraph 5.17 above) took explicit account of this possibility.⁹³

Are the Proposals capable of proper implementation and enforcement?

- 7.3 As I indicated at paragraphs 3.16(e) and 4.9(c), a second aspect of implementation and enforcement which is of relevance to the regulation of tobacco products - especially in respect of particular regulatory proposals with potentially far reaching consequences which are likely to affect a wide range of actors, e.g. manufacturers, retailers, minors and adults - is that any proposed measure must be assessed in terms of whether it is capable of being complied with. To adopt any regulation which is incapable of being complied with would simply be to replace market failure with a type of regulatory failure.⁹⁴

⁹¹ R Baldwin and M Cave, *Understanding Regulation*, 1999, p 37.

⁹² *Ibid*, p 96.

⁹³ DoH Consultation, p 100.

⁹⁴ One such example of regulation being implemented which is (in part) incapable of being complied with is the UK’s Proceeds of Crime Act 2002. This Act imposes certain obligations which are unrealistically burdensome. For example, the Act technically requires companies to report any circumstance which

- 7.4 A regulation that required a new food or tobacco packaging labelling change without providing for an appropriate minimum necessary transitional regime or to require the amount of a substance present in food to be labelled on packaging even though it is not scientifically possible accurately to record such levels (for example, nanoparticles) would provide a (hypothetical) illustration of this point. A further example, more closely related to the content of this report, would be a regulatory measure which banned the display of tobacco (or other) products in shops without giving retailers adequate time to put the products out of sight in a manner that not only complied with the measure, but is also viable from a security and logistical perspective.⁹⁵
- 7.5 It is important from a better regulation perspective for a regulator to consider whether existing measures are being effectively implemented and enforced before introducing further regulatory intervention. For example, in the case of prohibitions of sales of cigarettes to minors, is there an effective way of improving the enforcement of existing regulations? Taking England and Wales as an example, a possible option for ensuring that existing regulation such as the negative licensing regime and other youth access laws (which I consider more fully in section 9 below) are better enforced could be to provide greater resources and training to trading standard officers (*TSOs*). In England and Wales, *TSOs* are responsible for identifying incidences of underage sales/purchase and taking action when non compliance occurs. Greater resources may allow *TSOs* to carry out more ‘test purchasing’. It is also important from a better regulation perspective for the regulator to assess carefully whether measures such as the Proposals will be capable of proper implementation and enforcement. This is particularly so where the regulator is acting as a ‘first mover’ and introducing a measure (such as plain packaging) which has not been implemented anywhere else in the world.

8. BETTER REGULATION PRINCIPLES TO BE APPLIED TO TOBACCO PRODUCTS - THE PROPOSALS.

An introduction to the Proposals

- 8.1 As I indicated above at paragraphs 4.9(e) and 4.13(a), it is incumbent upon any regulator during the RIA process to consider alternative approaches (including, amongst others, the availability of alternative regulatory solutions with the potential to minimise or remove the risk of negative, unintended consequences) and to demand that different ways of reaching regulatory objectives are compared. In my view and based on my experience of assessing the design of regulatory policies to achieve economic, and also social, objectives, this is likely to be particularly important in the context of tobacco regulation, where - even intuitively -

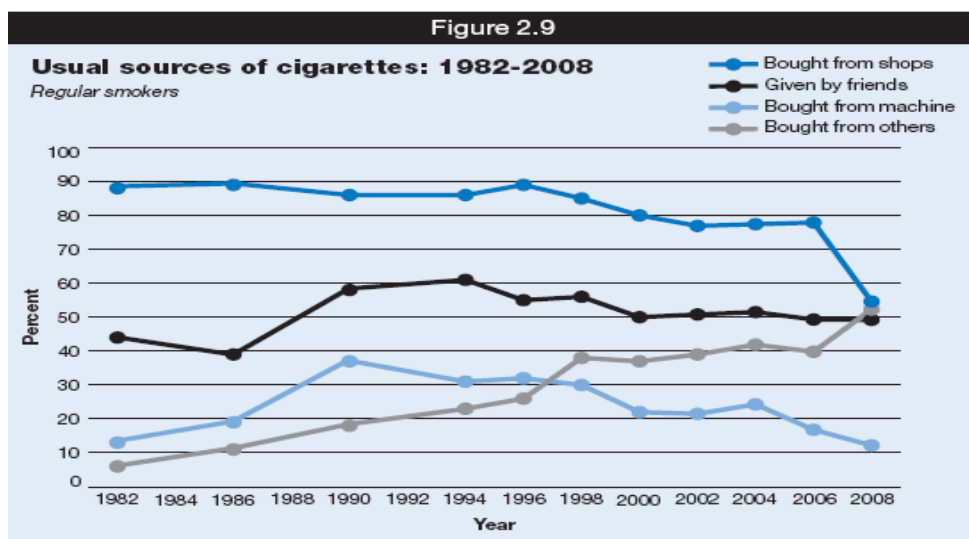
could amount to any offence under any legislative instrument, if it could result in that entity incurring any commercial benefit (such as a cost-saving). This technically requires reports to be made whenever a minor non-compliance with a requirement occurs, even where the responsible regulator is aware of and endorses the non-compliance, and where the non-compliance is routine (such as momentary breach of a water pH or noise limit in an environmental permit). For large companies, this could result in a large number of daily reports, which the Act was not designed to regulate, which would likely inundate the Serious Organised Crime Agency to the point of rendering it unable to fulfil its intended role.

⁹⁵ The BIS acknowledges that “*owners of small businesses often draw attention to the fact that legislation introduced quickly may not leave enough time for them to prepare, absorb and implement the changes*” (<http://www.bis.gov.uk/policies/enterprise-and-business-support/business-environment/implementation-periods>) and that “*many costs can be minimised if sufficient time is allowed e.g. changes to labelling requirements should allow enough time to use up existing stocks*” (<http://www.berr.gov.uk/files/file44371.pdf>), p 18.

there may be a number of alternative methods of varying intrusiveness and effectiveness in achieving the types of regulatory objectives considered in section 5 above.

- 8.2 Given that - as indicated above - measures like the Proposals are often expressly targeted to reduce smoking initiation by minors, it is useful to begin by looking at the evidence concerning how minors acquire their tobacco products. In this respect, I refer to the graph below (entitled Figure 2.9) taken from a report conducted on behalf of the UK's Department of Health in 2009,⁹⁶ and note the conclusion reached in that same report that:⁹⁷

“Pupils who smoked cigarettes, both regularly and occasionally, obtained cigarettes from a variety of sources. Most commonly, pupils reported being given cigarettes by other people (63%) and more than half were given cigarettes by friends (58% of smokers). A small proportion of pupils were also given cigarettes by their siblings (10%) and parents (6%). 45% of pupils who smoked cigarettes bought them from other people. This includes 33% who bought them from friends or relatives and 28% who bought them from somebody else.”



- 8.3 It is helpful to ask what regulations apply in respect of youth access to other goods and services of an ‘adult nature’. For example, no fewer than 13 groups of products and services are subject to age-related sales restrictions in the UK. These range from alcohol and tobacco to aerosol spray paint, imitation firearms, knives and fireworks. The age limits vary, most of them expiring at 16 or 18 years.

⁹⁶ E Fuller, Smoking, drinking and drug use among young people in England in 2008, 2009 (<http://www.natcen.ac.uk/media/492785/de84e05d-5326-42c1-b687-3d75416b7fbb.pdf>), p 26.

⁹⁷ In this respect I note the author’s statement that “this survey is the latest in a series designed to monitor smoking, drinking and drug use among secondary school pupils aged 11 to 15. Information was obtained from 7,798 pupils in 264 schools throughout England in the autumn term of 2008” (p 9).

8.4 These restrictions have recently been examined by a review group, largely consisting of representatives of the relevant retail outlets, reporting to the Local Better Regulation Office, a UK public body which deals with regulation enforced by local authorities.⁹⁸

8.5 Much of this report is concerned with the defences available to those found to be selling to minors and to the legitimacy of enforcement by ‘test purchasing’ – namely getting a minor to try to make a purchase. But the report also notes:

*“In addition, there is no consistent deterrent for prospective under-age purchasers of these products as the focus of penalties is very much on the seller - only alcohol has a penalty for the buyer attempting to buy under the required age. Similarly, other than for alcohol and intoxicating substances, often referred to as solvents, there are no direct offences for those buying on behalf of young people (‘proxy purchasers’)”.*⁹⁹

8.6 The report recommended that, in order to provide a better deterrent, all persons aged 14+ should be liable to a risk of sanction for deliberately attempting to obtain products to which they are not legally entitled. Similar sanctions should apply to adult ‘proxy purchasers’ and to minors asking an adult to purchase by proxy.¹⁰⁰

8.7 In respect of the objective of reducing smoking uptake/consumption by minors, both a proxy and youth purchase offence (as well as the other alternatives) which I consider below in section 9, may be identified by a regulator as an effective alternative to the Proposals because they would be more targeted. In my experience of regulatory economics and impact assessments, because measures like proxy and youth purchase offences are targeted and are therefore focussed upon a clearly identified and specific problem, this reduces the likelihood of them having unintended consequences. In these circumstances, it is my experience that such measures are also more likely to achieve their stated objective(s). Indeed, this is - in my view - the very essence of the better regulation agenda. Accordingly, it might be argued that as less intrusive and more targeted measures, it is appropriate to try a proxy purchasing and youth purchase offence (as well as the other alternatives) before, for example, mandating plain packaging. Thus the alternatives apparently satisfy the better regulation criterion of targeting and proportionality introduced in section 3 above.

8.8 It is in this context that I consider, as any preparer of a competent RIA would have to do, the extent to which the adoption of measures such as the Proposals are - relative to alternative approaches which I consider more fully in section 9 below - proportionate and targeted responses to achieving the types of regulatory objectives discussed in section 5 (such as restricting and/or preventing youth access to tobacco products).

Mandating larger health warnings

8.9 Next, I review the considerations which a regulator would, in my view, need to take into account in respect of a proposal to mandate larger health warnings on cigarette packs if the regulatory process is to conform to the better regulation requirements described above. This

⁹⁸ Better Regulation of Age-Restricted Products: a Retail View, 2010 (<http://www.lbro.org.uk/docs/age-restricted-products-report.pdf>).

⁹⁹ *Ibid*, p 4.

¹⁰⁰ *Ibid*, p 6.

raises the question of the appropriateness, as a matter of better regulation principles, of providing information or withholding it from actual or potential smokers about tobacco products themselves or the health risks associated with smoking them.

- 8.10 Mandating that information on health risks be printed on cigarette packs is generally a longstanding regulatory requirement. It was imposed a significant period of time ago in many jurisdictions (for example, in 1966 in the US¹⁰¹). On the face of it, when first introduced, the printing of a health warning on a pack is, as a matter of regulatory theory, a standard information remedy. I understand that it was designed to correct a perceived lack of information which caused a market failure (in this case the regulator's perception was that some smokers might not be aware of, or might require reminding of, the health risks of smoking). In this respect, it is somewhat like the warnings on alcohol which have been more recently introduced in numerous jurisdictions,¹⁰² some counselling restraint by all, others directed at particular groups such as pregnant women.
- 8.11 The issue in question now is not the use of health warnings for the first time, but whether mandating larger health warnings on cigarette packs would have, in the language of paragraph 3.16(d) above, a value incremental to existing measures. Applying better regulation principles to a larger health warnings proposal (including those of problem definition and thorough impact assessment), in my opinion, requires the development of an RIA which:
- (a) addresses (by reference to an evidence base of a quality and type described in section 6 above) whether there remains an information gap about the health risks associated with smoking that is of a nature requiring regulatory intervention;
 - (b) discusses, if such a gap is shown to exist, what options might exist to remedy the gap; and
 - (c) considers which of these options would be the most effective (in light of relevant expert and other evidence) at least cost.
- 8.12 I am not an expert in the issue of how (if at all) such an information gap could be remedied where one has been shown to exist. However, from my general experience of reviewing RIAs and commenting upon them, I would expect that the preparer of an RIA would need to analyse the effectiveness of various options in reaffirming or strengthening the message about the risks of smoking. Options to consider might include not only the ways in which more/different health risk information can be communicated through warnings on pack (see below as regards the question of changing the content of the health warning), but also using other vehicles (like the use of renewed public information campaigns).
- 8.13 There are two further special features of the tobacco case which deserve comment in this report and which I would expect to be addressed in any relevant RIA. The first is that the warning and manufacturer's information must both appear in the limited space on a cigarette packet. The second is that mandatory pictorial warnings are sometimes imposed in place of, or as well as, the more usual printed text. I comment on both below.

¹⁰¹ See footnote 72.

¹⁰² For example, France was the first country in the EU to pass such legislation when it did so in 2006, and is one of the few worldwide to use graphic logos warning against drinking alcohol during pregnancy.

The limited space on a cigarette packet

- 8.14 A revision of regulations affecting the warning required on packs is less intrusive as a matter of regulatory norms if it minimises the impact on the ordinary market process of manufacturing and selling cigarettes. It would therefore be appropriate, in accordance with the criterion of targeting and proportionality, for the preparer of an RIA to examine whether changes to the content of existing warnings are capable of achieving the regulatory objective before considering increasing the size of the warning. Clearly, a warning can potentially fulfil the dual purpose of reaffirming messages about the health risks of smoking (i.e. reinforcing information) and of expressly displacing the manufacturer's branding material (i.e. effectively proscribing access to certain information). But, unless the evidence base shows it is necessary for the health warning to be effective for it to take up a large amount of space on the front of the pack, better regulation principles mean that the goal of suppressing branding information requires separate justification (not least because of the intellectual property law issues likely to be engaged). It is arguable that the goal should be to empower the adult to make his or her own choices.

Pictorial health warnings

- 8.15 As to the use of larger health warnings containing photos, perhaps of a smoker pictured in the late stages of a smoking-related disease, there is perhaps a risk that such depictions cause distress to some. However, a regulator may find justification in better regulation terms for them if they could be shown to: (a) furnish better information than warnings in words alone; and (b) actually influence behaviour (e.g. not starting smoking). I am not able to provide an expert view on whether this is the case. I am aware, however, of a report by Dr Keegan which concludes, amongst other things, that cross-sectional wave survey evidence from Canada, the first country in the world to introduce pictorial health warnings covering 50% of the principal display surfaces of the pack, demonstrates that larger pictorial warnings there did not enhance awareness of the health risks of smoking or change smoking behaviour.¹⁰³
- 8.16 Finally, It would be of particular interest to the preparer of an RIA if the evidence base demonstrated that pictorial health warnings had a greater effect on minors' behaviour than on adults, as, for reasons noted above, there are not the same issues with over-riding their preferences as there are with adults' preferences.¹⁰⁴ It is for others, with the requisite expertise in fields like the study of adolescent development, to determine if this is the case. A challenge in this regard would occur if the warning - even with photos - were simply ignored by smokers (whether minors or adults).

¹⁰³ W Keegan, Analysis of Consumer Survey Evidence Relevant to Health Canada's Proposal to Increase the Size of Health Warnings on Tobacco Packaging, 2010, p 13.

¹⁰⁴ The UK Department of Health has acknowledged this. When considering proposals to ban cigarette vending machines, the Department noted that "*it might be argued that any life years saved here are not a legitimate benefit, as adults are entitled to smoke if they want to, but issues such as addiction may also be taken into account*" (DoH Consultation, p 100) (emphasis added).

Prohibiting the display of tobacco products in retail outlets and plain packaging

Issues common to both these Proposals

- 8.17 The two regulatory options reviewed here apply to all smokers, young and adult. Nonetheless, it is useful for regulators and those interested in better regulation to consider separately their impact on the two groups, as different objectives are in play. If either regulatory option had a significant and demonstrable effect in discouraging minors from starting smoking, then that alone might justify them, provided their impact on adults were either beneficial or not too detrimental.
- 8.18 Some analysis conducted by others as to the effect of these two Proposals which would be relevant to the criterion of evidence-based assessment is set out below. Here, however, I consider one issue of relevance to impact assessment which is common to both - that they may limit the arena of competition in which cigarette manufacturers operate. I consider this issue: (a) based on my expertise in regulatory economics, or the application of economic analysis to regulated sectors or activities; and (b) because any preparer of an appropriate RIA would - in my view - also have to do so. Prohibition of point of sale displays prevents a purchaser from exposure to another brand than the one he or she may have been proposing to purchase when approaching the point of sale. This may reduce consumers' knowledge of the market-place, and therefore the numbers of existing smokers who switch brands, and may therefore affect the pricing and other strategies which manufacturers adopt in order to encourage brand switching. In the opposite direction, there may be a reduction in costs and a greater focus on price competition. There may also be an effect on innovation.
- 8.19 Plain packaging risks carrying this effect further (not least given that, as a measure, it continues to play a role after the purchase has been made), assuming such a measure would reduce or even eliminate the value of the brand. There would also appear to be little point in having a display at point of sale of uniformly plain packs, even if it were allowed. The effects described in the previous paragraph would therefore be likely to be more pronounced, although I recognise that this is a hypothesis based on my experience as an expert in regulatory economics of similar measures in other contexts, given that plain packaging has not actually been introduced anywhere to date.
- 8.20 If the net effect of the prohibition of display and/or of the plain packaging measure were to be to raise prices, this would both restrict output and transfer resources from consumers to producers. To the extent that a pure transfer occurred, according to some it would be neutral. However, the increase in profit does not compensate fully for the loss of consumer benefit; accordingly there is a net loss. If this were to occur, it would be akin to a tax - a variant of 'taxation by regulation'.¹⁰⁵ This particular regulatory option may put up prices as a tax would, and may distort consumption of legitimate tobacco products as a tax does, but the revenue would be captured by the producers rather than the government.
- 8.21 As far as dynamic effects are concerned, the loss of competitive pressure may extend to restricting innovation. The lack of incentive to innovate in ways which require embodiment in packaging covers both the nature of the packaging itself and the opportunity to communicate product innovation on the package - an opportunity which assumes greater importance when other channels of communication are blocked (such 'blocking' has

¹⁰⁵ The role of regulation in putting up prices is analysed by R Posner, 'Taxation by regulation' in the *Bell Journal of Economics*, 1971, pp 22-50.

occurred frequently in a tobacco context as a result of a number of measures, such as advertising and sponsorship bans). Such innovation may enhance the willingness to pay of consumers and thus confer a consumer benefit. The innovation may range from being relatively costless to requiring substantial investment.

- 8.22 The earlier discussion of ‘taxation by regulation’ reminds us of the permanent availability of taxation as a potential means of influencing the consumption of legitimate tobacco products by minors and adults alike. Of course, the incidence of the tax may not fall on consumers, but be shared with them and producers, and the elasticities may be low. I am not aware of the point at which price hikes of legitimate product induce sales of counterfeit or contraband cigarettes. In my view, a full RIA would consider this too for the reasons I explain above.

Bans on displaying tobacco products in retail outlets

- 8.23 Prohibitions on display at the point of sale have been in place in various jurisdictions for several years in a number of countries, including Iceland, Thailand, Ireland, Norway and Canada (where introduction occurred at different dates in different provinces). The Health Act 2009 has paved the way for its staged introduction in England, Northern Ireland and Wales. I understand that similar legislation also exists in Scotland (see paragraph 5.12 above). Some Australian states and territories will introduce a ban from 2011. RAND Europe reports that “21 out of 27 EU Member States have already taken steps to limit promotion and displays at [points of sale] by restricting or banning some forms of advertising, although none has yet implemented complete bans on promotions and displays at retail stores”.¹⁰⁶
- 8.24 This means that ‘before and after’ data should be available to the preparer of an RIA on the effect on point of sale display prohibitions, and possibly other measures as well, as well as the normal studies based on reported perceptions and behaviour and micro studies.
- 8.25 In an ideal regulatory world, there would be an emerging consensus about the effects of display bans, which could guide future decision-making. This is the normal procedure in economic analysis in debates over the impact, for example, of monetary aggregates on economic activity and inflation. As evidence accumulates, disagreements may persist but they often become more focussed. I understand that this is not the case in this context, with there being disagreement as to the effectiveness of display bans in achieving goals such as reducing youth smoking initiation.¹⁰⁷
- 8.26 This state of affairs clearly makes it very difficult to perform a conclusive RIA.¹⁰⁸ More generally, law makers face an apparently irreconcilable conflict of evidence over whether the measure under consideration works.

¹⁰⁶ RAND Europe Report, p 192.

¹⁰⁷ See further, by way of example: J Padilla, The Effectiveness of Display Bans: the Case of Iceland, October 2009; A Lilico, Economic Analysis of a Display Ban and/or Plain Packs Requirement in UK, April 2008; A Lilico, The Impact of Restrictions on the Display Bans of Tobacco - A Supplemental Report, October 2009; and the RAND Europe Report, pp 192-193. The first three of these reports were prepared for tobacco product manufacturers.

¹⁰⁸ The RAND Europe Report suggests that Padilla’s study makes use of time series data which present particular statistical limitations, but the limitations are not described (p 194).

- 8.27 In these circumstances, good regulatory practice requires that the proposer of the measure commissions thorough empirical research which clarifies the issue. It would - in my view - normally be appropriate, as a matter of better regulation, to await that evidence before the regulator implemented such a measure.

Mandating plain packaging for tobacco products

- 8.28 This measure has not been implemented anywhere in the world, so there is no evidence of its effects in practice. This is an illustration of the ‘first mover’ scenario, which I discuss above at paragraphs 6.3 to 6.6 when considering the responsibility it places 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. For the reasons I explain above, the argument that the lack of such evidence rules out adoption of the policy should not be used, as it would prevent any novel regulatory option from being considered in the first instance. However, what is required in these circumstances is that the regulator or the preparer of the RIA rely only upon methodologically sound and meaningful predictive evidence or studies (if experts in the field conclude that predictive evidence can be reliably relied upon) as to the expected effect of any such regulatory option on influencing individuals’ behaviour. The regulator should scrutinise and then carefully consider the weight which should be attributed to such studies where they can be done well or badly. I am aware, for example, of written reports criticising a number of such studies.¹⁰⁹
- 8.29 I am not qualified to assess these criticisms, but anyone undertaking an RIA would have to take them into account. As I indicated at paragraph 4.13(g), it may also be appropriate to take account of other possible consequences such as compliance with international law obligations, but I have no expertise in this area and make no further comment.
- 8.30 More generally I note that the claims made by supporters of plain packaging in the papers noted above fall into various categories. One thread is that packaging is designed to attract consumers. Another assertion is that the colour of the packaging may influence perceptions of the health risks associated with the product.¹¹⁰ Another is that plain packs may increase the attention given to health warnings (it is unclear whether it is purported that this would actually enhance awareness of the risks of smoking or change smoking behaviour).
- 8.31 Correspondingly, the aspects of plain packaging which have attracted attention are the contentions made by its supporters that it:
- (a) reduces the ‘attractiveness’ of tobacco products, especially to minors;
 - (b) increases the impact of health warnings; and
 - (c) reduces ‘false beliefs’ relating to health risks.

¹⁰⁹ See, for example, J Padilla and N Watson, A critical review of the literature on generic packaging for cigarettes, a report for Philip Morris International, January 2010.

¹¹⁰ See for example: Australian Government, Taking preventative action – A response to Australia: The healthiest country by 2020 – The report of the National Preventative Health Taskforce, 2010 ([http://www.health.gov.au/internet/preventativehealth/publishing.nsf/Content/6B7B17659424FBE5CA25772000095458/\\$File/tpa.pdf](http://www.health.gov.au/internet/preventativehealth/publishing.nsf/Content/6B7B17659424FBE5CA25772000095458/$File/tpa.pdf)), p 66 and <http://www.ash.org.uk/media-room/press-releases/cigarette-pack-design-gives-misleading-smoke-signals>.

- 8.32 The key question for me as a matter of application of better regulation principles is whether the measure will have the desired effect. If not, then it lacks justification. Given that plain packaging has not been tried, it would be unreasonable (as I explain above) to require evidence from the ‘first mover’ of the measure’s effects in practice, as such a policy would rule out any regulatory innovation. But, in my view, better regulation principles require that there must be, in Advocate General Fennelly’s words, “*coherent evidence that the measure will be effective in achieving the public interest objective invoked ... and that less strict restrictive measures would not have been equally effective*” upon which the regulator can confidently rely, as well as “*reasonable grounds for adopting the measure in question in the public interest*”.¹¹¹
- 8.33 It is not controversial to suggest that firms, including cigarette manufacturers, design product packaging to encourage consumers to purchase the brand. However, it is necessary in an impact assessment to go one step further and estimate what is the net effect of plain packaging on smoking behaviour (such as initiation by minors), as well as the shares of the market gained by the various competing brands. Ideally this would require consumers revealing or stating their purchasing intentions in a world where all legally available cigarettes are in plain packaging. This is a regulatory environment that does not exist, however.
- 8.34 The RAND Europe study for the Commission concludes by reference to the goals of reducing cigarette consumption/initiation that:
- “Thus, given the importance of product attractiveness in product purchasing decisions and evidence that such packaging detracts from the health warning currently placed on such products, it is apparent that plain packaging would have some deterrent impact (albeit difficult to quantify) on the consumption of tobacco products. It might also be envisaged that that this impact could be greater in deterring consumers who are non-smokers and therefore not yet addicted to nicotine from taking up smoking”.*¹¹²
- 8.35 The problem with this conclusion is that, however plausible the existence of an effect may be, it is extremely difficult to evaluate its potential significance, because we do not know its scale. In terms of the other contentions made by supporters of plain packaging, namely that it may assist in generating more accurate perceptions of health risks and may combat false inferences about health risks, as indicated in the previous discussion, these can in my view (and given the better regulation principles I discuss in section 3) be legitimate objectives of regulation insofar as they actually change individuals’ behaviour. The main obstacle at present is the (in my view, remediable) lack of evidence permitting a calibration of the benefits.

What does this means for the three Proposals?

- 8.36 Returning to the concept of enhancing consumer protection by preventing over-regulation (see paragraph 2.10 above) it seems to me that some of the potential measures considered

¹¹¹ Advocate General Fennelly’s Opinion, paragraph 161.

¹¹² RAND Europe Report, p 134.

above (namely the Proposals) run the risk of: (a) being over-inclusive; and (b) conferring low or uncertain benefits.

8.37 In accordance with this observation and consistent with better regulation principles, it would be appropriate to exercise caution, not in order to protect producers, but as an ‘aiming off’ strategy which it is rational to adopt when the legislator is aware of the risk of excess regulation. I have referred above to the desirability, in the case of adult smokers, of avoiding illiberal solutions. Accordingly, in the section which follows, I consider possible alternative or complementary means of achieving the objectives that the Proposals are intended to achieve which - in my view, and consistent with better regulation principles - any regulator would have to give serious consideration to before turning to the Proposals.

9. THE AVAILABILITY OF ALTERNATIVE REGULATORY OPTIONS TO THE PROPOSALS.

9.1 As I have indicated elsewhere in this report, it is incumbent upon any regulator to consider possible alternative or complementary means of achieving the objectives that the Proposals are intended to achieve. Particularly in light of the conclusions reached in section 8 above, before adopting bans on displaying cigarettes in shops or requiring plain packaging, it is necessary to ask whether a portfolio of measures can be devised which can be targeted to achieve not only the objective of preventing youth access, but also legitimate public policy objectives relating to adults as well.¹¹³ Accordingly, I now consider a series of targeted and proportionate measures which should form part of such a portfolio.

9.2 As demonstrated by recent legislative activity, it is possible to criminalise the supply or sale of tobacco products by an adult, including relatives and friends, to a minor (a ‘proxy purchase’ offence), as well as criminalising the purchase or attempted purchase by that minor (a ‘youth purchase’ offence). In England and Wales, for example, the burden of responsibility is currently only placed on retailers to ensure that they do not sell tobacco products to minors under 18.¹¹⁴ A retailer’s only defence is to prove that he/she took all reasonable precautions and exercised all due diligence to ensure that the person was over 18.¹¹⁵ No risk is currently placed on the minors themselves or adults who buy or attempt to buy tobacco products on behalf of minors (i.e. the proxy purchaser).

Proxy purchase offence

9.3 In terms of a ‘proxy purchase’ offence, I understand that such laws have already been passed in all the states and territories of Australia. For example, in Victoria it has been illegal since 1987 (and punishable with a fine) for adults to purchase a smoking product for use by a person under 18 years old.¹¹⁶

9.4 Similarly, and as noted above in section 5, in early 2010 in Scotland, a proxy purchase offence was passed, which from April 2011 will make it illegal (and punishable with a fine)

¹¹³ It is pertinent that preventing minors from taking up smoking is also very likely to affect adult smoking in the future.

¹¹⁴ Children and Young Persons Act 1933 (<http://www.legislation.gov.uk/ukpga/Geo5/23-24/12/contents>), s. 7(1).

¹¹⁵ Children and Young Persons Act 1933 (<http://www.legislation.gov.uk/ukpga/Geo5/23-24/12/contents>), s. 7(1A).

¹¹⁶ Tobacco Act 1987 (Victoria) (http://www.austlii.edu.au/au/legis/vic/consol_act/ta198773/), s. 12.

for a person aged 18 or over to buy or attempt to buy a tobacco product or cigarette papers on behalf of a minor under the age of 18.¹¹⁷

- 9.5 Although not included in the final version of the UK Health Act 2009, tobacco proxy purchase offences were debated in the British House of Lords and the House of Commons with many calls for there to be parity between alcohol and tobacco laws relating to proxy and youth purchase offences. Typical of these calls was that made by Earl Howe, who in the context of debate in the House of Lords on the provisions of the Health Bill (as it then was) stated that:

*“Proxy purchasing, far from being uncommon, is the most serious component part of youth access to tobacco...Here it is true that the burden of evidence required to prosecute a proxy purchaser creates an enforcement challenge and that there are barriers in the way of action on this front, mainly to do with resources. However, recent developments in the enforcement of alcohol legislation show that it is possible and can be cost-effective”.*¹¹⁸

- 9.6 In a similar vein, Mike Penning MP¹¹⁹ (then Shadow Health Minister) noted in the House of Commons debate in relation to the same legislation that:

*“While it is understandably illegal for someone to proxy-purchase alcohol and pass it on to a minor, it is not illegal to proxy-purchase cigarettes and pass them on to a minor. I do not understand that. If the measure is to protect young people, and I genuinely broadly support it, I do not understand why [a proposed proxy purchase offence] is not accepted [...]”.*¹²⁰

- 9.7 In my opinion, a proxy purchasing offence has the potential to build further on the apparent success of raising the age of the persons to whom cigarettes can legally be sold in the UK, illustrated in Figure 2.9 at paragraph 8.2 above. A proxy purchase offence is also a measure targeted against minors’ access to cigarettes. It seeks to close off a significant avenue by which minors get cigarettes. It has no collateral effect on the non-proxy adult purchasers. The risk of criminal prosecution may act as a deterrent on adults, despite other motivations which they may have in supplying cigarettes to minors, such as misguided affection. These are all aspects which can be investigated either by stated preference methods or, in Scotland from April 2011, by revealed behaviour. I have no basis for forecasting the results of these investigations, but they seem to be both practicable and useful.

¹¹⁷ Tobacco and Primary Medical Services (Scotland) Act 2010 (<http://www.legislation.gov.uk/asp/2010/3/contents>), s. 6.

¹¹⁸ 9 March 2009 (<http://www.publications.parliament.uk/pa/ld200809/ldhansrd/text/90309-gc0004.htm>). Earl Howe went on to provide the example of an initiative in St Neots in Cambridgeshire (UK), where local agencies worked with retailers and focussed resources on deterring and detecting underage alcohol sales using a combination of intelligence-led action against proxy sales and confiscation powers. As a result of this approach, Earl Howe reported that *“a real reduction in underage drinking in the town was achieved, and the enforcement costs were no different from more standard enforcement approaches”*.

¹¹⁹ Member of Parliament for Hemel Hempstead (Conservative).

¹²⁰ 12 October 2009 (<http://services.parliament.uk/hansard/Commons/ByDate/20091012/mainchamberdebates/part005.html>).

Youth purchase offence

- 9.8 Another intervention which would fall for a regulator to consider as a matter of better regulation principles is the creation of a ‘youth purchase’ offence. Such an offence already exists in Singapore, where it is illegal for a minor under 18 years old to buy any tobacco product whatsoever.¹²¹
- 9.9 Similarly, and as noted above in section 5, in early 2010, a youth purchase offence was passed in Scotland, which from April 2011, will make it illegal (and punishable with a fine) for a person under the age of 18 to buy or attempt to buy a tobacco product or cigarette papers.¹²²
- 9.10 As indicated above, this type of offence has already been tried before in the UK, as well as in other jurisdictions (including, for example Australia), notably in relation to alcohol purchases. In England and Wales it is an offence for a minor under 18 to buy or attempt to buy alcohol, as well as for a person aged over 18 to buy or attempt to buy alcohol for a minor under 18 years old.¹²³
- 9.11 As in the case of a proxy purchasing offence, criminalising purchases by minors is a targeted measure. The risk of criminal prosecution may also act as a deterrent on minors, despite other motivations which may exist for minors when attempting to purchase cigarettes, including, for example, peer pressure from other minors, or the desire to act rebelliously. There are, though, legitimate questions which would have to be considered by the regulator about the desirability of subjecting minors to further criminal charges. The measure has been adopted in relation to cigarettes in Singapore for nearly two decades, and will come into effect in Scotland in April 2011. Moreover, such an approach has been tried widely in relation to the purchase of alcohol. A 2007 US study on the effects of alcohol regulation concluded that *“there is strong evidence that the enhanced enforcement of laws prohibiting the retail sale of alcohol to minors is an effective method of reducing such sales”*.¹²⁴ It is worth investigating, therefore, whether the same outcome can be replicated in relation to tobacco.

Consumption by minors in public offence

- 9.12 The above options are, of course, not the limit. Other options for criminal sanctions, already in use in relation to alcohol, include laws prohibiting minors from smoking in a public place.

¹²¹ See Smoking (Control of Advertisements and Sale of Tobacco) Act (Act 10 of 1993) (http://statutes.agc.gov.sg/non_version/cgi-bin/cgi_retrieve.pl?&actno=Reved-309&date=latest&method=part), s. 11. I understand that the Singapore authorities have not conducted an assessment of the effectiveness of this measure. I have not sought to do so by reference to official smoking behavioural data. I note however that the Singapore authorities have published information generally on youth smoking. See, for example, the National Smoking Control Campaign 2010 (<http://www.hpb.gov.sg/news/article.aspx?id=7950>).

¹²² See Tobacco and Primary Medical Services (Scotland) Act 2010 (<http://www.legislation.gov.uk/asp/2010/3/contents>), s. 5.

¹²³ Licensing Act 2003 (<http://www.legislation.gov.uk/ukpga/2003/17/contents>), s. 149.

¹²⁴ Transportation Research Board of the National Academies, ‘Traffic Safety and Alcohol Regulation: A symposium, June 5-6, 2006, Irvine, California’ in Transportation Research Circular, no. E-C123, November 2007 (<http://onlinepubs.trb.org/onlinepubs/circulars/ec123.pdf>), p 187.

Such a law has been enacted in Singapore, where - I understand - it is illegal (and punishable with a fine) for those under 18 years old to smoke tobacco products in public places.¹²⁵ I understand that Alberta in Canada is another example of somewhere where, since 2003, a similar offence exists.¹²⁶

- 9.13 As indicated above, such an approach mirrors laws already in place (notably in a number of states in Australia) prohibiting minors from drinking alcohol in public. For example in the state of Victoria, a minor caught drinking or in possession of alcohol in public is guilty of an offence and can be fined.¹²⁷ In the UK, it is illegal (and also punishable with a fine) for a minor under 18 to drink alcohol in a licensed place such as a club, restaurant, pub or off-licence.¹²⁸
- 9.14 As above, such a prohibition may have a deterrent effect on minors and has the potential to limit 'out of home' smoking by them. It is targeted and, subject to general issues associated with criminalising actions by minors, may be proportionate.

Negative licensing

- 9.15 Further interventions to prevent minors purchasing tobacco products include a form of licensing of outlets for tobacco. This can be either 'positive' or 'negative'. Under the former system, a retailer has to apply for a licence before making a sale, and that licence can be withdrawn in the event of any infraction of the 'selling to minors' rule. Under negative licensing, a retailer notifies a body set up for that purpose of its intention to sell tobacco. In the event that it is found to have broken the rules, its licence can be withdrawn under what are sometimes known as 'tobacco retailing banning orders'.
- 9.16 Negative licensing already operates in a number of jurisdictions. In England and Wales, for example, I understand that a negative licensing regime has been in operation since 2009.¹²⁹ In England and Wales, retailers can sell tobacco products without a licence, but they risk losing this right if they are caught selling tobacco or cigarette papers to minors under the age of 18 years on three (or more) occasions within a two-year period. The retailer can either be banned from selling tobacco products in a particular shop or banned from selling tobacco products at all.
- 9.17 A negative licensing scheme is also in place in other jurisdictions, for example in Saskatchewan in Canada, where since 2002, a retailer can be banned from selling tobacco if they are convicted more than once in a three-year period for selling tobacco to minors, with

¹²⁵ Smoking (Control of Advertisements and Sale of Tobacco) Act (http://statutes.agc.gov.sg/non_version/cgi-bin/cgi_retrieve.pl?&actno=Reved-309&date=latest&method=part), s. 11.

¹²⁶ Prevention of Youth Tobacco Use Act (Alberta) (<http://www.canlii.org/en/ab/laws/stat/rsa-2000-c-p-22/latest/rsa-2000-c-p-22.html>), s. 2.

¹²⁷ Liquor Control Reform Act 1998 (Victoria) (http://www.austlii.edu.au/au/legis/vic/consol_act/lcra1998266/), s. 123.

¹²⁸ Licensing Act 2003 (<http://www.legislation.gov.uk/ukpga/2003/17/contents>), s. 150.

¹²⁹ Children and Young Persons Act 1933 (<http://www.legislation.gov.uk/ukpga/Geo5/23-24/12/contents>), ss. 12A and 12B.

the length of the probation increasing each time the retailer is convicted, with the retailer liable to a fine on each occasion they are caught selling tobacco products to minors.¹³⁰

- 9.18 This measure goes to influencing the actions of the retailer not the purchaser or smoker. The data exhibited at paragraph 8.2 above shows a significant decline in the proportion of those aged 11 to 15 buying cigarettes in shops following the year 2007, when the legal purchasing age was raised from 16 to 18 in England. This is consistent with retailers responding to changes in the law which alter the balance for them of commercial reward and risk in undertaking certain transactions.

Restrictions on cigarette vending machines

- 9.19 A final measure aimed at prohibiting sales of tobacco to minors involves restrictions on cigarette vending machines. As noted above, absent age verification controls, these machines constitute a means by which minors acquire tobacco products.¹³¹ They also pose in very clear terms the issue of whether it is necessary, in order to deny access to minors, to deny access to adults as well. This is because access to cigarette vending machines can be made conditional - i.e. authorised for adults but not for minors.
- 9.20 The UK Department of Health identified three possible cigarette vending machine age restriction mechanisms: use by the purchase of an electronic age verification card; a process which requires the purchaser to obtain from a staff member an ID coin; and remote control by a staff member.¹³² The cost-benefit analysis also considered the option of banning vending machines entirely. This would impose a loss of convenience on adult smokers, and may confer health benefits if they reduced cigarette consumption. It was noted that: "*It might be argued that any life years saved here are not a legitimate benefit, as adults are entitled to smoke if they wish, but issues such as addiction may also be taken into account*" (emphasis added).¹³³

What does this mean for any regulator considering the Proposals?

- 9.21 In summary therefore, it is apparent from the above discussion that a number of interventions are available which are expressly targeted at preventing minors from acquiring cigarettes. Given that this is an express goal of policy,¹³⁴ it would be natural (and consistent with better regulation principles) for any regulator to give these serious consideration before other measures like the Proposals.
- 9.22 I am not in a position to evaluate empirically the relative merits of interventions which are directed at altering the behaviour of the three parties identified in the above discussion - the retailer, the minor and the adult proxy purchaser. More generally, however, I am aware of a systematic review carried out in 2000 and published in a peer reviewed journal, which

¹³⁰ Tobacco Control Act (Saskatchewan) (<http://www.canlii.org/en/sk/laws/stat/ss-2001-c-t-14.1/latest/ss-2001-c-t-14.1.html>), s. 23.

¹³¹ It can be seen from the table at 8.2 that in the UK at least, vending machines are not a significant 'usual source' of cigarettes for minors (approximately 10% in 2008).

¹³² DoH Consultation, p 93.

¹³³ *Ibid*, p 100.

¹³⁴ See, for example, paragraph 5.13 above.

analysed studies of intervention for preventing tobacco sales to minors.¹³⁵ While recognising the difficulty of establishing the relationship with retailer behaviour in abiding by laws relating to selling to minor and minors' overall access to cigarettes, the authors conclude that regular enforcement (4-6 times a year) is effective. Enforcement across a local area is important; otherwise retailers argue that they are forgoing revenue to no overall benefit. The studies show that compliance will not be total. Retailers may be deceived, or may sell to minors whom they know, and are not therefore 'test purchasers'. The emphasis in these conclusions on effective enforcement calls to mind the criterion of 'incremental effect' noted above - that an RIA of new measures should also consider the alternative of improving the effectiveness with which existing measures are implemented. It is important to do this in any RIA for the Proposals discussed here.

10. CONCLUSIONS.

- 10.1 The question which I have addressed in this report concerns the approach which should be taken to evaluating the regulation of tobacco products. In my view, there are good grounds for regulating tobacco, a product with significant health risks, but the process of deciding how to regulate deserves the same careful specification of objectives, identification of alternatives and weighing up of evidence as does regulation of other areas.
- 10.2 The process should be informed by recent advances in the best practice of regulation known generically as the better regulation agenda, widely accepted and adopted by many countries. This agenda seeks to impose certain requirements on regulation. It does so because the application of the better regulation agenda (whatever the context) improves the transparency, inclusiveness and integrity of regulatory processes. I have suggested above that the better regulation principles can be summarised as: clarity of objectives, targeting and proportionality, evidence-based assessment, incremental effect, and enforceability.
- 10.3 In relation to the objectives of tobacco regulation, I have identified distinctions between objectives relating to minors (whose preferences can be over-ridden) and relating to adults (who are granted more autonomy). Recognising this distinction suggests targeting proscriptive measures on curtailing smoking by minors.
- 10.4 Because there are several measures available, it is essential to have clarity of objectives and a clear specification of options. According to the principle of targeting and proportionality, preference should be given to less intrusive measures first.
- 10.5 The construction of a careful RIA is essential to ensure that the best option is chosen. The evidence base for its selection should be the best available and reliable. Consideration should be given to a range of options, including better enforcement of existing measures. Because the protagonists in the debate are so deeply divided, and because the evidence base has been called into question, governments and regulators should be prepared to commission new disinterested research to resolve disputes of fact.
- 10.6 Measures such as the Proposals target minors and adults. Increasing the size of health warnings or changing from text to pictorial ones, may be an information remedy where the need for such a remedy has been reliably determined. Prohibitions of display and plain

¹³⁵ L Stead and T Lancaster, 'A systematic review of interventions for preventing tobacco sales to minors' in *Tobacco Control*, 9, pp 169-176.

packaging have elements of prohibition and thus require more careful evaluation. Prohibition of display is associated with a serious conflict of evidence over its effectiveness, which should be addressed by a regulator before proceeding.¹³⁶ Plain packaging is untried; this is in no way a reason to reject it, but the evidence basis for introducing it should include a careful assessment of its likely effects and whether equally effective and more targeted measures should be applied first.

- 10.7 In relation to the objective of preventing or reducing smoking by minors, there appear to be a number of alternative targeted measures available - the combined effect of which may have a deterrent impact on minors - including criminalising buying by minors and proxy adults and negative licensing. Some of these are, or will be in the future, employed in relation to tobacco products in some jurisdictions, and some of them are also employed in relation to alcohol. In my opinion, this experience should be taken into account by regulators considering measures like the Proposals.
- 10.8 For the avoidance of doubt, I acknowledge that (with the exception of questions relating to regulatory and market economics), I am not qualified to make the technical judgements of evidence which should underlie a proper RIA for the measures under discussion, and I am in no way prejudging the outcome of such an assessment. My observations in this report solely concern the standards which I consider such an assessment should meet to conform with principles of better regulation now widely accepted by governments and regulators.

¹³⁶ See paragraphs 8.25 - 8.27 above.

SCHEDULE

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| 1987 to 2001 | Professor of Economics, Brunel University. |
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Appointed by the **Secretary of State for Transport** to chair an expert panel on airport regulation, April 2008 – November 2009.

Appointed by the **Chancellor of Exchequer and Secretary of State for the Environment** to undertake a review of competition and innovation in the UK water industry, March 2008 – April 2009.

Member, **UK Payments Council**, 2007 – 2010.

Adviser to **Industry Canada** on spectrum policy, 2007.

Appointed by the **Secretary of State, Department of Communities and Local Government** to undertake review of the regulation of social housing, 2006 – 2007.

Special adviser to **European Commissioner Viviane Reding** on the reform of telecommunications regulation, 2006.

Appointed by **Chancellor of Exchequer** to conduct review of major spectrum holdings, December 2004 – November 2005.

Adviser to **Lord Chancellor's Department** on legal deregulation 2004 – 2005.

Member, **Ofcom Spectrum Advisory Board (OSAB)**, 2004 – 2007.

Economic Adviser, **Ofcom**, 2003 – 2007.

Member, **DEFRA** regulatory task force, 2003.

Non-Executive Advisory Director, **OFWAT**, 2002 – 2006.

Appointed by **Chancellor of the Exchequer and the Secretary of State for Trade and Industry** to prepare an independent report on spectrum management, March 2001 – March 2002.

Adviser, **Postal Services Commission**, 2000 – 2007.

Adviser, **Civil Aviation Authority**, 2000 – 2003.

Member, **Spectrum Management Advisory Group, DTI**, 1999 – 2003.

Member, **French Ministry of Finance**, Groupe d'Expertise, electricity grid pricing, 1999.

Member, **UK Competition Commission**, 1996 – 2002.

Economic Consultant, **Office of Utility Regulation (Jamaica)**, 1998 – 2000.

¹³⁷ Consultancy assignments from firms omitted.

Member, **OFGAS** Panel of Economic Experts, to advise the Director General of Gas Supply on a variety of economic issues relating to regulation of the industry, 1994 – 1999.

Member, **Office of Fair Trading**, 1990 – 1992 and 1995 – 1999. Acted as Broadcasting Adviser to the Office of Fair Trading in matters relating to the regulation of networking arrangements for the television industry (1990 – 1992). Adviser on BSkyB Inquiry (1995 – 1996). Expert witness for the Director (1998 – 1999).

Member, **French Ministry of Posts and Telecommunications**, Groupe d'Expertise – advisory committee on universal service and interconnection, 1991.

Adviser to the **Ministry of Agriculture, Fisheries and Food** on appropriate procedures for tendering for the decommissioning of the fishing fleet, 1993 – 1996.

Economic Adviser to **HM Treasury** undertaking advisory work on a consultancy basis for the Public Enterprise Analytical Unit and the Economics of Industry Division involving participation in the design of regulatory regimes for the water and electricity supply industries during privatisation. Secretary to an Inter-Departmental Group reviewing the discount rate and rates of return in the public sector, 1986 – 1990.

Consultant to the **Home Office** Committee on financing the BBC, chaired by Sir Alan Peacock, advising on cost and revenues, 1985 – 1986.

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