Reducing regulation: Consultation for businesses and civil society organisations – Response by Action on Smoking and Health
March 2016

National Audit Office

NAO Questions

1. What, in your experience, are the costs and benefits of regulations?

2. How does regulation impact on your organisation?

3. Do departments and regulators consult your organisation when measuring and evaluating the actual impact of regulation?

About ASH

1. Action on Smoking and Health ("ASH") is a campaigning health charity that works to eliminate the harm caused by tobacco. It was established in 1971 by the Royal College of Physicians. The organisation is headed by its Chief Executive, Deborah Arnott, and is governed by a Board of Trustees. Its Patron is HRH the Duke of Gloucester. ASH provides the secretariat for the All Party Parliamentary Group on Smoking and Health. Its funding is provided principally by Cancer Research UK and the British Heart Foundation. ASH has also received specific project funding from the Department of Health for work on the implementation of Government tobacco policy.

Why We Are Responding to this Consultation

2. ASH is responding to this consultation because we consider that the current policy rules about reducing regulation, and in particular the application of the recently announced "One in Three Out" (OITO) rule, militate against regulations to protect and improve public health, and will deter Government departments from introducing such regulations even where it can be convincingly shown that the wider social and economic benefits of regulation are greater than the costs to business that regulation imposes. We do not have a position of principle in respect of deregulation, but we do suggest that an effective deregulatory agenda (that does not do more harm than good) needs a more sophisticated approach than blanket application of the OITO rule.

General Principles

3. Cigarettes and other tobacco products are uniquely harmful to health. One in five people in the UK still smoke, and 100,000 people in the UK die prematurely every year from smoking related disease.[1] Smoking-related disease places a huge burden on NHS services. Currently the cost to the NHS of treating people with diseases caused by smoking is £2bn a year in England alone. But the total cost to society, which includes costs to employers, families and the environment, is conservatively estimated to be £13.9 billion a year.[2] Investment in public health, including tobacco control, is therefore essential to reduce health care costs as well as the misery and suffering that smoking causes. Tobacco control measures such as the Stop Smoking Services and mass media campaigns are proven to be highly cost effective.[3]

4. To reduce the harm caused by smoking, which has been a key public health objective for successive Governments, requires a very high level of policy intervention, including appropriate regulations. A comprehensive strategy including a range of regulations

introduced from 1998 onwards has been highly effective, and is estimated to have prevented 70,000 premature deaths due to smoking.[4] Smoking rates in Great Britain have fallen by nearly a third amongst adults from 27% to 19% [5] and by more than two thirds, from 10% to 3% among children aged 11-15 between 2000 and 2014.[6] During this time a comprehensive set of regulations were brought into effect including:

- Large health warnings on cigarette packs (2002)
- Comprehensive ban on advertising promotion and sponsorship (from 2003)
- Smokefree enclosed public places (2007)
- Age of sale of 18 for tobacco (2007)
- Picture warnings on cigarette packs (2008)
- Prohibition of sale from vending machines (2011)
- Point of sale display ban (large shops 2012 and small shops 2015)
- Prohibition of smoking in cars with children (2015)
- Prohibition of proxy purchasing of tobacco (2015)

Any single regulatory intervention is part of a broader comprehensive approach to tobacco control and all components are necessary for success. Initially regulatory policies can impose burdens on business. But designed properly the burden of regulation can be minimised, and regulation limited to those which are necessary and proportionate to the policy objectives they are designed to achieve. A good example is smokefree legislation, which the Better Regulation Executive itself has cited as a case study of effective regulation[7], which was considered by over 80% of business decision makers to be a 'good idea', led to significant improvements in air quality in pubs and bars, and achieved compliance rates over 95% from the outset.[8]

5. In order to continue to drive down smoking prevalence rates, regulation and related policy interventions must be *progressive*, since anyone who still smokes or now starts to smoke has in effect discounted previous regulatory measures. It is also relevant that policy levers to reduce smoking prevalence work best together, so that the effect of the whole is greater than the sum of the parts. For example, a move to the standardised ("plain") packaging of tobacco products will be most effective if supported by mass media campaigns, continuing tax rises and well-funded local provision to help smokers trying to quit. Such policies are often best introduced by regulation rather than on a voluntary basis, as this ensures consistency in approach and also prevents businesses from gaining an unfair competitive advantage.

6. Tobacco control, together with other areas of public health policy, therefore does not easily fit within a simplistic and uniform approach to regulatory reform, particularly the OITO rule. The rule, as currently applied, is demonstrably in conflict with other key policy objectives. For example, the latest NHS Five Year Forward View states that *"the future health of millions of children, the sustainability of the NHS, and the economic prosperity of Britain all now depend on a radical upgrade in prevention and public health Twelve years ago Derek Wanless' health review warned that unless the country took prevention seriously we would be faced with a sharply rising burden of avoidable illness. That warning has not been heeded - and the NHS is on the hook for the consequences."* [9]

7. It is relevant that public health budgets around the country are now under increasing pressure. In June 2015 the Chancellor announced £200 million in-year cuts to DH funding for local authority controlled health budgets, amounting to a 7.4% cut to what is supposed to be a ring-fenced budget. [10] Further cuts to public health budgets of £600 million in real terms by 2020/21 were made as a result of the 2015 Spending Review. [11] With such serious cuts to public health budgets, it is even more essential that policies which encourage behaviour change at population level are implemented, as these are

likely to be the most cost-effective and effective way of achieving the necessary *'radical upgrade in prevention and public health'*.

Key Recommendations

8. This consultation response makes two recommendations:

    - ASH recommends that the OITO rule should be reformed so that in assessing cost and benefits due consideration is given to costs and benefits to society overall and not just to business. Alternatively there should be an exemption for public health measures, in the same way as regulations on civil emergencies and financial systemic risk are exempted.

    - The OITO rule should be reformed so that any compensating deregulatory action required when a new regulation is introduced does not necessarily have to be taken by the Department introducing the new regulation. This is particularly important in relation to the Department of Health, for the reasons given below.

    - As a matter of urgency, the OITO rule should be reformed so that the distinction between "direct" and "indirect" costs to business does not operate in a way that effectively discriminates against public health regulation.

The "One In Three Out" principle

9. Future regulations to protect public health are threatened by the Government's "One In Three Out" (OITO) policy, which forces Government departments to remove regulations worth twice the cost to business of any new regulation they introduce. To quote the explanation for the one in two out (OITO), now three out, policy on the DBIS website: [12] *"To reduce the number of new regulations for businesses, the government operates a 'one-in, two-out' rule. This prevents government policymakers from creating new regulations that increase costs for business and voluntary organisations. When policymakers do need to introduce a new regulation, and where there is a cost to complying with that regulation, they have to remove or modify an existing regulation with double the cost to business."* ASH believes that, as it is currently stated, the OITO principle sets an unreasonable hurdle for new public health regulations.

10. For example, if tobacco control regulations lead to smokers buying less tobacco, this is counted as a "cost" to business, while the benefits to the wider society are not properly considered. It is appropriate that costs to business of regulation should be considered in deciding whether a regulatory measure is effective, and cost-effective, but not that this should be the determining factor.

Impact of OITO on Department of Health

11. The burden of meeting the OITO standard falls on individual Government departments, which have to find regulations to get rid of worth double the cost to business for any new regulation they wish to introduce, with no account taken of the wider benefit to society of such regulations. As set out in the BRE Ninth statement of regulation, published in December 2014: *"Departments will be held to account for their overall performance under the OITO rule in the six-monthly Statement of New Regulation, and at the end of this Parliament (assessed from January 2013). Departments who were in One-in, One-out deficit at the end of 2012 will also need to ensure they achieve One-in, One-out when considered over the entire Parliament."* [13]

12. While we are of course pleased that regulations have been passed to require the standardised 'plain' packaging of tobacco products, we are deeply concerned that the Department of Health is consequently required under the OITO rule to remove regulations with costs to business of twice the value of lost profits to tobacco companies as a result. The primary purpose of the Department of Health is to *"help people stay in good health and live independent lives*", not to regulate business. [14] It is particularly difficult for the DH to find regulations to remove, particularly since it has been removing regulations since 2010, first under 'One In One Out', then since December 2012 under the 'OITO' rule, and from now on under the 'One In Three Out' rule. It is likely in future that either the introduction of desirable new public health regulations (defined as desirable when the overall benefits to society are fully considered against economic and social costs) will be blocked, or the Department will be required to remove regulations that still perform an important function in improving health.

Regulatory Policy Committee and Restrictive Interpretation of Costs and Benefits

13. This problem has been made worse by the decision of the Regulatory Policy Committee, an independent advisory body under the Department of Business, Innovation and Skills, that any regulations which drive down industry profits count as an 'in' for the purposes of OITO, while any benefits to business from changing purchasing behaviour by consumers are not taken into account. So, for example, tobacco regulations which reduce cigarette sales are counted as a 'cost' to business, but consequential spending by consumers on products other than tobacco are not counted as a 'benefit'. No clear explanation has been given as to why the RPC has made this change, as according to the BIS Better Regulation Framework Manual, most recently updated in March 2015, only direct impacts to business should be scored for OITO. [15]

14. Point 81 of the DH Impact Assessment of the standardised packaging regulations states: *"Only direct impacts on business should be counted for OITO purposes. Losses of profits to tobacco companies and others in the supply chain due to reduced consumption of tobacco are contingent on the changed behaviour of smokers and so were excluded from OITO calculations in previous tobacco IAs. The Regulatory Policy Committee have now advised that policies which ban or severely restrict a particular activity, that explicitly prohibit a form of promotional activity, and have a primary objective to reduce sales (even if by promoting behaviour change) should be considered as having a direct impact on businesses. Whilst the primary reason for the TPD2 is to harmonise rules across the EU, this legislation is explicitly attempting to maintain a high level of health protection. In this IA we therefore treat profit losses resulting from the expected reduction in tobacco consumption as a direct impact for OITO purposes. We note that the Better Regulation Executive's Framework review is considering the question of the definition of "Direct" for OITO purposes."* [16]

15. It should be noted that lost tobacco sales were counted as an indirect impact by the DH for the consultation stage Impact Assessment for the draft standardised packaging regulations. This IA stated that *"Losses of profits to tobacco companies and others in the supply chain due to reduced consumption of cigarettes or downtrading are an indirect effect (as agreed for legislation to end the display of tobacco in shops) and out of scope for OITO."* [17] As a result there was a zero net cost to business at consultation stage. However, at the final stage, because the RPC changed its advice, the IA was revised to include as direct costs due to behaviour changes which reduce smoking prevalence, which are precisely the intention of the policy. To be specific this includes as a cost the anticipated drop in the number of smokers and downtrading among those who remain smokers, and the impact of these behaviour changes on the profits to retailers, wholesalers and tobacco manufacturers, while no countervailing benefit is included for these behaviour changes.[18] [19]

16. The primary purpose of tobacco regulation is of course to reduce the number of adult smokers and the number of young people taking up smoking. If reductions in tobacco industry sales and profits can be counted against any public health benefits from regulations designed to cut smoking rates, then virtually any tobacco control regulations would count as an 'in' for the purposes of OITO. Two thirds of current smokers started before their 18th birthday. One in two lifetime smokers will die from smoking-related disease. This is a deadly addiction, very difficult to escape, and therefore in no meaningful sense a free choice by smokers. It cannot be right for lost profits to tobacco manufacturers and retailers to be used as a reason not to proceed with measures which have as their main purpose reducing tobacco consumption. The current Government, its Coalition predecessor and the previous Labour Government all agreed that reducing tobacco consumption to nil is a long term objective.

17. Although the introduction of standardised packaging will go ahead, there is now a precedent which could be used to stop further public health regulations, for fear they would result in lost sales to business. Around one in three 11-year-olds in the UK is overweight or obese, and obesity, together with smoking, drinking and lack of physical exercise are the leading causes of avoidable death and disease. The Health Select Committee in its report in 2015 on the impact of physical activity on diet and health recommended that the Government takes steps to stop the marketing of unhealthy food and sugary drinks to children.

18. However, any strengthening of the current rules on advertising to children may be prevented by the rules on reducing regulation, which could in future catch in its remit independent regulators such as OFCOM. Reducing sales of unhealthy foods, or in reducing advertising revenues, would count as a regulatory 'in' requiring the removal of another regulation worth twice the cost to business, while the benefits in reductions in obesity and related diseases such as type 2 diabetes would be considered irrelevant. It is appropriate that costs to business of regulation should be considered in deciding whether a regulatory measure is effective, and cost-effective, but this should be surely considered in conjunction with the potential wider social and economic benefits of such regulation.

19. This problem has a wider impact than simply the regulation of consumer products, tobacco or alcohol. For example, following scandals about the treatment of the vulnerable and elderly in care homes the benefits of increased regulation to the public were not included in the impact assessment of revised regulations, while the costs to business were included, so that in order to bring in regulations to improve market oversight the DH had to commit to removing regulations "worth" twice the amount to business.[20]

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[1] ASH Fact sheet: Smoking statistics: Illness and death. ASH, Nov 2015
[2] ASH Fact sheet: The economics of tobacco: ASH, Dec 2015
[3] Inquiry into the effectiveness and cost effectiveness of tobacco control: All Party Parliamentary Group on Smoking and Health, Oct 2010
[4] Smoking Still Kills. London. ASH. 2015
[5] Opinions & Lifestyle Survey: Adult smoking rates in Great Britain, 2014 ONS, 2016
[6] Smoking, drinking & drug use among young people in England, 2014 HSCIC, 2015
[7] Better Regulation Executive. Better Regulation, Better Benefits: Getting the Balance Right. DBIS May 2009.
[8] Smokefree England one year on. DH. 2008
[9] NHS England: Five Year Forward View: Executive Summary point 3

[10] Government announces £200m cuts to public health budget: Pulse 5 Jun 2015
[11] Spending Review 2015: what does it mean for health and social care: Nuffield Trust, Health Foundation, Kings Fund, Dec 2015
[12] One in two out: statement of new regulation: Dept for Business Innovation & Skills, July 2013
[13] The ninth statement of new regulation. Better Regulation Executive Dec 2014
[14] Corporate Plan 2014-2015: Department of Health, Jun 2014
[15] Better regulation framework manual: Par 1.9.11 Dept for Business Innovation & Skills, Mar 2015
[16] Standardised Packaging regulations: Department of Health Impact Assessment 5 Mar 2012
[17] Standardised packaging of tobacco products. Consultation stage: Department of Health Impact Assessment 17 Jun 2014
[18] Standardised packaging of tobacco products: Department of Health Impact Assessment 10 Feb 2015
[19] Opinion: Standardised packaging of tobacco products: Regulatory Policy Committee 9 Feb 2015.
[20] Market Oversight in Adult Social Care. Department of Health Impact Assessment 26 Mar 2013.