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ONE

Introduction

1.1 Tobacco is a uniquely dangerous consumer product, killing 120,000 people per year in the UK and 4 million worldwide when used as intended by the manufacturer. Cigarettes are highly addictive, and are the most toxic and carcinogenic means of delivering nicotine. They are also heavily promoted and widely available.

1.2 In February 2000, the Royal College of Physicians' Tobacco Advisory Group published an extensive, authoritative account of the role of nicotine in British society, *Nicotine addiction in Britain*. The final two recommendations of that report were:

> *14. Tobacco products in Britain should therefore be regulated either by the Medicines Control Agency or by a nicotine regulatory authority similar in concept to the Food Standards Agency.*
>
> *15. We recommend that an independent expert committee should be established to examine the institutional options for nicotine regulation, and to report to the Secretary of State for Health on the appropriate future regulation of nicotine products and the management and prevention of nicotine addiction in Britain.*

1.3 In June of 2000, the Commons Health Select Committee examined the issue in detail and arrived at a similar conclusion, endorsing the recommendation of the College and adding:

> *189. […] It seems to us entirely illogical that treatments for nicotine replacement therapy are subject to stringent regulation whereas the infinitely more deadly tobacco products they are designed to supersede escape any fundamental regulation. So we believe a Tobacco Regulatory Authority should be introduced.*

1.4 The purpose of this report is to take those recommendations forward and to encourage the government to address the strategic issue of how it should regulate the tobacco industry and tobacco and other nicotine products. This report considers the regulatory challenges that lie ahead and are already evident, and examines various institutional and legal structures for regulation, based on three models. These are the Irish Office of Tobacco Control, the Medicines Control Agency (MCA) and the Food Standards Agency (FSA).

1.5 The report examines the options for regulation at European level (the stated preference of the Government) and the options available in UK law to create the necessary regulatory capacity.

TWO

The case for a tobacco and nicotine regulatory authority

2.1 This document argues that considerably more regulatory capacity for tobacco is required and justified in order to protect public health in the UK. The impact of tobacco on British society is quite unprecedented – consider eight aspects:

1 **The scale of the impacts of tobacco use.** 10 million users are addicted to nicotine, and tobacco-related disease kills 120,000 per year (one fifth of all deaths). It is responsible for one third of cancer, one seventh of cardiovascular disease and most chronic lung disease in adults. Tobacco is the single largest cause of social inequalities in health and aggravates poverty among poor smokers. There are multiple impacts on non-smokers and children exposed to tobacco smoke. There are pronounced economic impacts on the public sector (especially the NHS) and on productivity in the economy. It is the largest cause of fires with fatal injury and creates the single largest source of litter.

2 **The challenges of developments in the tobacco market.** Tobacco companies are designing products which claim reduced risk or other benefits, and smokeless tobacco producers are seeking to exploit very large reductions in risk compared to smoking. At the same time, novel nicotine products are coming to market that could greatly reduce harm, but face regulatory barriers far greater than cigarettes – the most harmful means of delivering nicotine.

3 **The complexity of the policy responses.** The policy responses require skilled programme management in order to spend money and expend resources wisely. Some may be scientifically complex, such as regulating the chemistry of smoke and tobacco products. Some policies are highly contentious, such as banning tobacco advertising, raising taxes and securing smoke-free areas. Some responses may give rise to unintended consequences, for example some youth initiatives may encourage smoking. In the area of smoking cessation, strict regulatory systems for pharmaceutical nicotine clash with the much weaker regime for tobacco, causing perverse outcomes that harm smokers.

4 **The current regulatory imbalances.** At present, nicotine replacement therapies are strictly controlled under medicines regulation, and oral tobacco is banned completely under European Union (EU) law – yet both represent much less hazardous ways of administering nicotine than cigarettes and both may be used for smoking cessation. However, cigarettes are subject only to the most cursory regulation and restrictions. This perverse regulatory imbalance favours the most deadly means of delivering nicotine.

5 **The strength of the commercial interests.** The UK industry is highly profitable, achieving profit margins of about 40% on turnover after deduction of duty. There are three FTSE 100 companies and major multinationals such as Philip Morris and Japan Tobacco International are involved at UK, EU and international level.

6 **The money involved.** Tax revenue raised from this sector is £9.3 billion per year in duties and VAT. This exceeds the monies committed in the tobacco white paper, *Smoking Kills*, by 250 times. Closer regulation of this industry in the interests of consumers is a modest return to those who pay their tobacco taxation. The whole enterprise should be funded by levies on the tobacco industry at no net cost to the public purse.

7 **Precedents from other areas of policy.** The government benefits from considerable regulatory capacity in the area of food and pharmaceuticals. Other governments are establishing reasonable regulatory capacity for tobacco.

8 **The 'pitiful' resources currently devoted to regulating tobacco.** No other area of public health policy has such large stakes in health, welfare and the economy, combined with such a complex and contentious policy environment and such large sums of money involved. Against this background, the Health Select Committee described the regulatory capacity for tobacco within government as 'pitiful' and at EU level 'utterly derisory'.

THREE

Forthcoming regulatory issues in tobacco policy

3.1 The following are examples of issues that already arise or are likely to arise in the regulation of tobacco products over the next few years.

The emergence of reduced-risk tobacco products

3.2 Manufacturers have already introduced products in the United States that they claim offer smokers reduced risks. Products include those making false, implied claims, such as 'lights'; products with certain carcinogens or other toxins selectively reduced; novel technologies such as heating rather than burning tobacco; and smokeless tobacco products to be chewed or sucked. In each case there are marketing claims made and applications suggested.

3.3 These present multiple challenges for regulators.

- What reduction in risk does the product achieve and how is this measured? The ISO tar yield measurements are of no use.
- What happens when some risks increase and others decrease?
- What claim may be made for the reduced risk, and who will give approval or regulate such claims?
- At what level of reduced risk would the authorities be negligent in not allowing consumers to be informed about products that do them less harm?
- How should claims that are true but may be misunderstood or understood disproportionately ('reduced cancer risk') be dealt with?
- How should relevant consumer information reach the consumer in a situation where advertising is prohibited?
- How should the market testing of such products be handled?
- What should government policy be in this treacherous area of public health?

The scope for reducing harm caused by mainstream cigarettes

3.4 There are technologies and techniques available that may reduce the harm caused by smoking by reducing hazardous chemicals in the smoke: what scope is there to *impose* technical performance standards on tobacco product manufacturers – what legal basis could be used? How would such standards be set and monitored?

Smokeless tobacco

3.5 As a way of using nicotine, the consumption of non-combustible tobacco is of the order of 10–1,000 times less hazardous than smoking, depending on the product. Some manufacturers want to market smokeless tobacco as a 'harm reduction' option for nicotine users, and they may find support for that in the public health community.

3.6 This raises many questions.

- Should the ban on oral tobacco (EU Directive 2001/37/EC article 8) be lifted and what kind of regulatory regime should replace it?
- Can product 'purity' standards be used to reduce the toxins in smokeless tobacco?
- What claims could be made about the relative health risk of smokeless tobacco and smoking and how should these be communicated?
- How can the use of smokeless products as a 'starter' product for young smokers be minimised?
- How can the risk of unintended consequences (eg reduced cessation) be minimised?
- How would the government and EU respond to a successful legal challenge to the EU ban on oral tobacco?
- How should 'smokers' rights' to have access to products that do them much less harm be reconciled with possible negative consequences at the population level?
- What options are there to 'promote' smokeless tobacco as a much safer alternative to smoking, without promoting tobacco use per se?

Pharmaceutical regulation of nicotine products: the level playing field

3.7 There may be 'harm reduction' indications for pharmaceutical nicotine, which involve long-term use or use during temporary abstinence from smoking. There are pharmaceutical products in the pipeline that may be branded more like tobacco products with a view to appealing to smokers. How is it possible to avoid letting the far more onerous pharmaceutical regulation keep such products from the market, while the almost non-existent regulation of tobacco allows cigarettes to be widely available with minimal safety restrictions or warnings?

Use of pure nicotine as a consumer alternative to smoking

3.8 There may be a generation of nicotine products that are offered outside the conventional pharmaceutical and medical framework as consumer products. One company has placed nicotine water on the market and another wished to offer a nicotine gum packaged and branded as an alterative to smoking. Such developments offer the potential for competition with cigarettes with much lower health impacts, but may also create new population risks.

Legal challenges

3.9 The tobacco industry has shown that it will challenge any meaningful public health measure on tobacco. Even if the measure cannot be overturned, the effect is to delay implementation, to tie up official time and to 'chill' the government's determination to regulate in this area. All of which means that legislation must be as robust as possible, offer a proper public health benefit and be robustly defended. The legal challenges to tobacco product regulation threaten a precipitous destruction of the government's policy on consumer protection for tobacco products.

3.10 This raises several questions:

- Why was legislation which in places is at variance with best available scientific knowledge written in the first place? For example, the Royal College of Physicians' February 2000 report, *Nicotine Addiction in Britain*, illustrated how tar-yield reductions offer little benefit to contemporary smokers.
- What scientific and public health capacity is available to work with lawyers to defend against legal challenges brought by the tobacco industry?
- How can UK regulation be made consistent with EU law and international trade agreements, while still achieving its aim of protecting public health, and who will gather the evidence?
- Are the trade-related treaties – World Trade Organisation (WTO) agreements, Trade-Related Aspects of International Property Rights (TRIPS) and the EU single market – adequately framed to protect health? Should the UK press for a public health article in the EU treaty?

Warnings on packaging

3.11 The UK will have to decide if it wants to include pictorial warnings on packs following the Commission's specification of how such warnings might be used. A regulatory committee will be established with the power to modify the warnings specified in EU Directive 2001/37/EC, but what are the appropriate warnings for the UK and how would these be determined?

Additives and design features

3.12 The regulation of additives is wholly inadequate in the UK and EU. How can a proper public health assessment be made of the impact of individual tobacco additives and what sort of approval process would be needed? What more could be done to force the introduction of fire-safe cigarettes?

Successor directive

3.13 EU Directive 2001/37/EC contains provisions for a review to be completed by 2004, with new proposals to follow if necessary. How will the UK government address the many areas that will be covered by the review and provide good scientific advice to the Commission?

Research agenda

3.14 Tobacco companies clearly know a great deal more about tobacco products than their regulators. What funds can be justified for research into tobacco products and how should these be spent?

Other areas of tobacco policy

3.15 The items listed above reflect just one aspect of tobacco policy – the regulation of the product and its packaging. There is also government regulatory involvement in a number of other areas of the tobacco market.[1]

- **Advertising, sponsorship and promotion – monitoring, enforcement, and legislative development.** The Tobacco Advertising and Promotion Bill allows for modification of the legislation in response to changes in technology and marketing practices.
- **Smoking in the workplace and public places.** The Health and Safety at Work Act places obligations on employers to protect the health, safety and welfare of employees. How should the scientific evidence on passive smoking be reconciled with the requirements on employers to do what is reasonably practicable to offer protection to workers?
- **NHS treatment of tobacco dependence.** There are several areas in which the Government defines policy and regulation of smoking cessation.
- **Taxation and economic effects.** There is a strong case to gather and analyse much greater data on the impact of tax policy both in shifting patterns of consumption and any unintended consequences.

Knowledge and experience

3.16 In addition to regulation and enforcement, there is a need for authoritative scientific, economic and public health advice and research to inform policy and regulation. Programmes with substantial funding, such as the national tobacco education campaign, also need to draw on best available knowledge of what works and programme experience from elsewhere.

1. See Action on Smoking and Health (ASH), 'Tobacco legislation, regulations and voluntary agreements', http://www.ash.org.uk/html/policy/legislation.html<8 November 2002 (Last accessed 13 November 2002)>

FOUR

Views of Parliament and Government responses

4.1 After an extensive review of the history of tobacco regulation in the UK and the role played by the tobacco industry, the Commons Health Select Committee made the following observations and recommendations:

> *189. The final conclusion of the RCP in its Report* Nicotine Addiction in Britain *was that 'an independent expert committee should be established to examine the institutional options for nicotine regulation, and to report to the Secretary of State for Health on the appropriate future regulation of nicotine products and the management and prevention of nicotine addiction in Britain'. We concur. It seems to us entirely illogical that treatments for nicotine replacement therapy are subject to stringent regulation whereas the infinitely more deadly tobacco products they are designed to supersede escape any fundamental regulation. So we believe a Tobacco Regulatory Authority should be introduced.*
>
> *190. We have, throughout our report, indicated areas for which we think a Tobacco Regulatory Authority (TRA) could take responsibility. It could look at all aspects of the marketing of tobacco, the product itself and the nature of its health risks and developments in respect of 'safer' cigarettes. […]*
>
> *191. Consequently we would envisage the creation of a TRA with its own scientists, completely independent of the tobacco companies. When considering its function we should like to stress that we do not believe that the TRA could, for example, seek the elimination of nicotine from cigarettes. Its policies would have to recognize the realities of a global market for tobacco products, where any attempt to exclude nicotine – which would in our view be tantamount to prohibition of cigarettes, in that nicotine is, in the words of the RCP, the 'unique selling point' of cigarettes – would be likely to be counter-productive. The proposed TRA could, however, examine nicotine:tar ratios to determine how these could be optimised to minimise exposure to toxins.*
>
> *192. The TRA would, as we have stated, be the ideal objective judge of which additives and flavourings should or should not be permitted to be added to tobacco products, having as its test the overall impact on public health. The TRA could consider the marketing of tobacco products, looking at areas of promotion going beyond advertising into issues such as point of sale displays.*
>
> *194. In a research capacity, the TRA could examine, and offer definitive statements, on the current scientific consensus as to the dangers of smoking, and could examine the most effective ways of persuading people to quit or never to start.*
>
> *195. Assuming there is a will on the part of Government to tackle nicotine addiction in the very fundamental way that we propose, the question remains where should a TRA be located? One possibility would be for the UK to have its own TRA, in a way analogous to the Food Standards Agency or Medicines Control Agency; another would be for a TRA to be located in Europe, the source of much of what currently passes for tobacco regulation. […]*
>
> *198. Turning to the question of how the TRA should operate we think it vital that such a body should be very well resourced to deal with the huge scientific and legal resources of the tobacco*

companies. We think that a proportion of tobacco duty should be hypothecated to finance the regulatory authority. In oral evidence the DoH told us that, to analyse and understand the technical composition of cigarettes, it relied on a scientific adviser, Professor Frank Fairweather, who worked one day a week, another scientific advisor working two days a week, and Mr Tim Baxter who worked full time. Mr Baxter explained that, as head of the Tobacco Research Unit, he had access to a technical advisory group via the Scientific Committee on Tobacco and Health. Finally the DoH provided over £500,000 a year to the Laboratory of the Government Chemist to test tar and nicotine ratings. Mr Baxter recognized there were many calls on the Department's resources, but he admitted that it would be 'very nice' to have more resources since his team were 'highly stretched'. When we put our concerns on this matter to the Secretary of State he agreed that the tobacco team in the Department was 'quite small', but he contended that its work was supplemented by, for example, the professionals working in Health Action Zones and the Scientific Committee on Tobacco and Health. This latter body he described as 'a very useful organisation'.

199. We would have more faith in the Secretary of State's assessment of the added benefit of SCOTH had that organization not been in abeyance for almost two years. We regard the current staff resources devoted to tobacco control, especially in the area of scientific knowledge and advice, to be pitifully weak. Irrespective of whether the Secretary of State accepts our recommendation that root and branch reform is needed in terms of a TRA, we would expect to see a major increase in resources, met out of the enormous income the tobacco companies pay in duties to the Treasury.

200. If UK staff resources are pitiful, those in the EU are utterly derisory. As the Secretary of State informed us, and as we saw for ourselves in Brussels, in Europe 'there is just one official dealing with tobacco', Mr John Ryan. In fact the situation is graver still, in that tobacco forms only one half of Mr Ryan's portfolio. We met Mr Ryan on our visit to Brussels and were extremely impressed by his knowledge and commitment. But we do not see how the Health Commissioner can deliver his objective of reducing tobacco consumption with such scant resources. We recommend that the Secretary of State makes immediate and urgent representations in Brussels to create a far more substantial unit to combat the enormous resources of the tobacco industry. We believe that European policy is already hugely compromised by the CAP subsidy, and that unless appropriate resources go into tobacco control European action in this sphere will lack credibility. [2]

4.2 The government's response dealt with these recommendations in a cursory manner:

The Government agrees with the Select Committee that tobacco products need to be regulated more effectively than at present. We believe that much of this regulation will be most effective if it is done at the European level, which is why we continue to argue strongly for tighter regulation and greater openness in negotiations with our European partners. The Draft European Directive on the manufacture, presentation and sale of tobacco products requires much greater openness, something which the UK has argued for strongly in Europe. Once adopted, we will be implementing the Directive.[3]

4.3 However, there is little sign of effective regulation at the European level, and indeed such regulation may not even be possible without a change to the EU Treaties. At present the treaties

2. House of Commons Select Committee on Health. *The tobacco industry and the health risks of smoking. Second report, session 1999/2000.* London: The Stationery Office, 2000.

3. Department of Health. *Government response to the second report of the Health Committee: the tobacco industry and the health risks of smoking*. London: DH, 2000.

emphasise the operation of the single market and do not allow regulation by qualified majority for health protection. In our view, it would be unduly constraining to require regulation of tobacco to fit within the single market provisions of the treaty – see the discussion in Appendix 2.

4.4 Evidently dissatisfied, the Health Select Committee raised the matter again in its report on public health:

> *248. We would welcome a clear statement of principle by the Government on the desirability of a Tobacco Regulatory Authority. We feel that our report was one of the most comprehensive analyses of the tobacco industry ever undertaken in the UK, had access to documentation that had hitherto been concealed, and got very much to the heart of the behaviour of the tobacco companies. We would like the Government unequivocally to support our recommendation and – when parliamentary time permits – introduce appropriate legislation to support it.*[4]

4.5 In its response, the Government offered a more open-minded view than its previous response to the Committee's report:

> *The Government agrees that there is a need for tighter regulation of tobacco products, and more information about the additives used in them and their effect upon health.*
>
> *It also agrees that there is a need for greater control of the contents of tobacco products and more information about the effects on health of the various ingredients. However, the Government is not convinced that all existing legislative powers have been fully applied and is considering how these might be used to regulate tobacco products more effectively. Wide-ranging powers exist under the Consumer Protection Act 1987 to ensure the safety of consumer goods, and the Government will not hesitate to use these, if necessary, to ensure that changes are made to tobacco products so as to reduce the harm these cause. That said, it is not in principle opposed to the idea of a Tobacco Regulatory Authority, should existing mechanisms prove inadequate, and will keep this whole area under review.*
>
> *The Government continues to believe that work in this area will be most effective at a European level and good progress is being made. The Directive of the European Parliament and Council on the manufacture, presentation and sale of tobacco products (2001/37/EC) came into force on 18 July 2001. This Directive will require Member States to collect thorough details of the contents of tobacco products on the market and to submit these to the European Commission, which in turn will be required to draw up a report on its application. The Directive requires that the Commission will be assisted by the necessary scientific and technical expertise.*[5]

4. House of Commons Select Committee on Health. *Second report, session 2000/1*. London: The Stationery Office, 2001.

5. Department of Health. *Government response to the House of Commons Select Committee on Health's second report on public health.* London: DH, 2001.

FIVE

Resources for tobacco: Department of Health 'regulatory' staff

5.1 A key criticism made by the Health Select Committee was that government resources devoted to regulating tobacco were 'pitiful' at UK level and 'utterly derisory' at EU level. However, since the publication of the Committee's report, the position has not improved and may actually have deteriorated. There has also been a rapid turnover of key staff, leading to loss of continuity and experience.

- At the Department of Health branch head level (civil service grade 5), there have been four senior officials in the last five years.
- At the team leader level (grade 6 or 7) there have been three complete changes of staff in five years. In the most recent change, the team leader has assumed wider responsibilities.
- The science and medical capacity was regarded as inadequate at the time of the Health Committee report in 2000, and has since been reduced. An experienced full-time medical officer has been replaced by a part-timer new to the field.
- The Department was previously able to draw on a pool of experience and expertise at the Health Education Authority – there was a team of ten professionals in 1999, but there are now only two part-time staff devoted to tobacco at its successor, the Health Development Agency. Though there have been some compensating increases in resources in the Department's communications and policy units, the government has lost a substantial body of expertise.
- The Scientific Committee on Tobacco and Health relies on voluntary and unpaid participation by established scientists in the field. After its 1998 report, it was in abeyance for more than two years. The Committee was reformed in late 2000 and has since met approximately quarterly. The Committee itself has registered concerns about its own level of resources, time commitment and expertise in relation to the scale of scientific challenges which lead to problems in its effective functioning.
- The Health Committee spoke highly of the experienced Commission official, Mr John Ryan. Mr Ryan has since been moved. The European Commission does have a slightly larger team now, but comprised of less experienced officials. It also has greater demands on its time due to legal actions by tobacco companies.

5.2 This is not intended to be a criticism of civil service career structures. However, it does suggest that the government needs an institutional solution to the problem of regulating tobacco that may be in some way separate from the Department of Health's Cancer and CVD Prevention branch. This would be similar to the approach taken towards regulating drugs and food, whereby external agencies exercise statutory powers and advise the Secretary of State on the use of his powers.

The Royal College of Physicians' view

5.3 The Royal College of Physicians urges the government to act on its commitment to tighter regulation and at least to follow the recommendation of the College's 2000 report *Nicotine addiction in Britain*:

> *We recommend that an independent expert committee should be established to examine the institutional options for nicotine regulation, and to report to the Secretary of State for Health on the appropriate future regulation of nicotine products and the management and prevention of nicotine addiction in Britain.*[6]

5.4 The College maintains that the regulation of tobacco and conduct of tobacco policy needs to be addressed at an institutional level – and that this means creating a permanently staffed agency with adequate responsibility and authority to create a proper regulatory environment for tobacco.

6. Royal College of Physicians. *Nicotine addiction in Britain*. London: RCP, 2000.

SIX

Regulating tobacco at the European level

6.1 The Government has argued that tobacco should be regulated at the European level and that any regulatory agency needs to be established at the EU level. There are a number of reasons why this is an insufficient response to the challenge.

- The institutions do not exist at EU level and the government has done little to press for them to be established. The tobacco product directive 2001/37/EC establishes a regulatory committee to deal with three narrow areas of regulation and requires that the Commission takes appropriate scientific advice in reviewing the effect of the directive. However, this does not amount to a proper regulatory authority.
- The government is ultimately responsible to the British electorate for positions adopted in the EU, and needs to place British interests to the fore while EU regulation and legislation is made. Where the regulatory capacity is weak at EU level and in other member states, the UK should not find itself agreeing with weak or inappropriate measures (as happened with 2001/37/EC) simply because it has, as stated by the Health Select Committee, 'pitiful' resources devoted to the issue.
- The competence of the EU to regulate for public health is at best ambiguous and the EU regulations in place governing tobacco are primarily to ensure the operation of the single market and compliance with trade agreements. The government therefore has the scope (and obligation) to introduce tobacco regulation for public health and consumer protection purposes as UK legislation or regulation – this has been the case for the advertising legislation. This will remain the case as long as the EU treaties (eg article 152) do not allow negotiation of binding directives or regulations at EU level for public health reasons.
- Enforcement and operation of EU laws are the responsibility of member states and there are many issues that arise at national level in the practical implementation of EU regulation.
- In the case of food and pharmaceuticals, the regulatory agencies are at both national and EU level, with very substantial agencies (the FSA and MCA respectively) in the UK. A similar structure should apply to tobacco.
- Regulation of tobacco at EU level has not been a conspicuous success so far (see Appendix 2 for a discussion of the limitations of tobacco regulation at EU level). This is mainly because tobacco legislation in this arena has been formulated under *single market* articles of the EU Treaties rather than as *health* legislation. Any regulatory body would also be formulated in the same way. Thus its dominant pre-occupation would be operation of the single market rather than public health.

SEVEN

Comparison: The Office of Tobacco Control, Ireland

7.1 In Ireland, new tobacco control legislation completed its passage on 27 March 2002. Part of the bill was to establish the Office of Tobacco Control (OTC). The legislation gives the following functions to the Office at section 10:

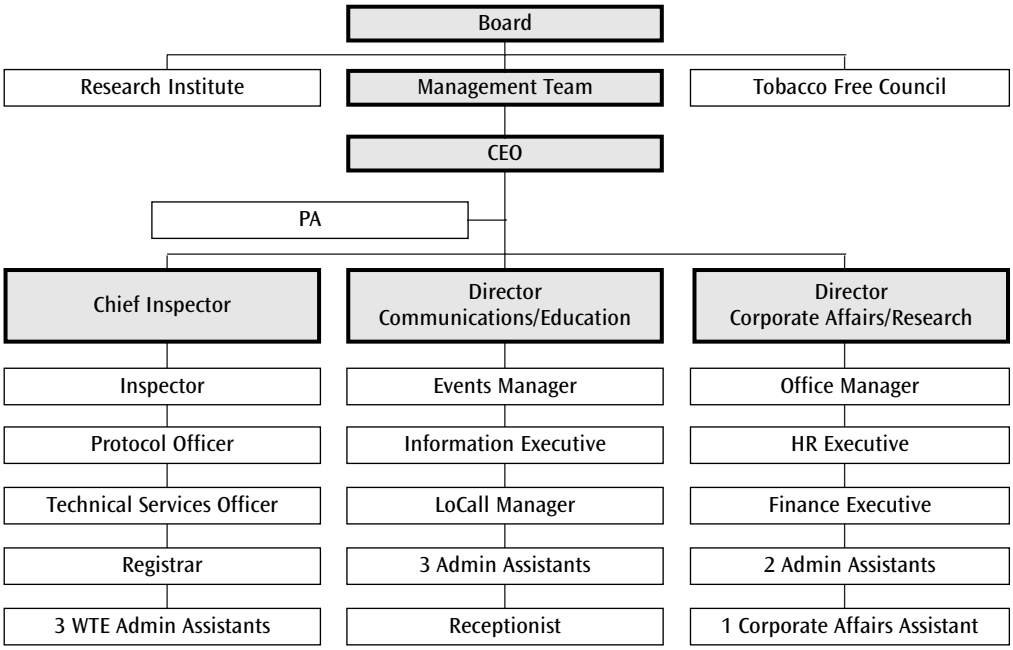
> *10.–(1) The general functions of the Office shall be to –*
>
> *(a) advise the Minister in relation to the formulation, and assist him or her in the implementation, of policies and objectives of the Government concerning the control and regulation of the manufacturing, sale, marketing and smoking of tobacco products,*
>
> *(b) consult with such national or international bodies or agencies having a knowledge or expertise in the field of smoking prevention for the purpose of identifying measures designed to eliminate, reduce the incidence of, or discourage smoking,*
>
> *(c) make such recommendations to the Minister as it deems appropriate in relation to measures that the Office considers should be taken in order to reduce or eliminate smoking or its effects in the State,*
>
> *(d) undertake, sponsor or commission, or provide financial or other assistance for, research aimed at identifying measures that when adopted are likely to reduce the incidence of smoking or its effects,*
>
> *(e) prepare and publish, in such manner as it thinks fit, reports on any research undertaken, sponsored or commissioned, or for which financial or other assistance was given, under paragraph (d),*
>
> *(f) furnish advice to the Minister, whenever he or she so requests, on matters relating to the control and regulation of the manufacture, importation, sale or supply of tobacco products and on measures to reduce, eliminate or discourage smoking,*
>
> *(g) provide, and where appropriate exchange with the Garda Siochana and the Revenue Commissioners, information relating to the control and regulation of the manufacture, sale, supply, importation and distribution of tobacco products,*
>
> *(h) prepare and implement a plan for the coordination nationally of the activities of the Office and of health boards in relation to this Act and the cooperation of the Office and the health boards in the performance of their functions under this Act,*
>
> *(i) furnish advice to the Minister, whenever he or she so requests, on matters relating to –*
>
> > *(i) strategies employed by manufacturers, importers, distributors or retailers of tobacco products in the marketing, sale or promotion of such products,*
> >
> > *(ii) technology used in the manufacture, production or marketing of tobacco products,*
> >
> > *(iii) any innovations on the part of manufacturers, importers, distributors or retailers of tobacco products relating to the manufacture, production or marketing of those products,*

(j) coordinate and implement a programme for the inspection of all premises in which tobacco products are manufactured, stored, subjected to any process or sold by retail, and all premises to which the public have access, either as of right or with the permission of the occupier or person in charge of the premises concerned, for the purposes of ensuring that there is compliance with the provisions of this Act,

(k) collect or disseminate such information as may reasonably be necessary for the effective performance of its functions,

(l) furnish, whenever the Office considers it appropriate or is so requested by the Minister, advice or information to a Minister of the Government (including the Minister) in relation to any matter connected with its functions.[7]

Fig. 1 **Organisation chart of the Office of Tobacco Control, Ireland.**



7.2 The role of the Board is described in section 12 of the Act:

12.–(1) The Office shall consist of the following members, that is to say, a chairperson and 11 ordinary members.

(2) The members of the Office shall be appointed by the Minister.

(3) The chairperson of the Office shall hold office for a period of 5 years from the date of his or her appointment.

(4) An ordinary member of the Office shall hold office for such period not exceeding 5 years as the Minister may determine when appointing him or her.

(5) A member of the Office whose term of office expires by the effluxion of time shall be eligible for reappointment to the Office.

7. Government of the Republic of Ireland. Public Health (Tobacco) Bill 2001. March 2002.

7.3 The role of the Tobacco Free Council is described in section 22 of the Act:

> *22.–(1) The Office shall establish a body to be known as the Tobacco Free Council (hereafter in this section referred to as the 'Council').*
>
> *(2) The Council shall make themselves available to be consulted by the Office in relation to the performance by the Office of functions (of such a class as may be determined by the Office, with the consent of the Minister) and may give advice or an opinion to the Office regarding any matter (of such a class as may, with the consent of the Minister, be determined by the Office) falling to be decided by the Office or the performance by it of such functions.*

Budget

7.4 The OTC is part of a comprehensive programme outlined for Ireland, *Towards a Tobacco-Free Society*.[8] The programme was budgeted at IR£20 million per year (UK£15.6 million) of which IR£600,000 was allocated to the OTC and IR£100,000 to the Tobacco Free Council. The final budget has yet to be settled (in July 2002).

7.5 The population of Ireland is 3.8 million, compared to 56 million for the UK. There are about 7,000 tobacco-related deaths per year in Ireland, compared to 120,000 for the UK. If Britain spent equivalent in per capita terms to Ireland's OTC and Tobacco Free Council, the budget would be £8.8 million.

8. Tobacco-Free Policy Review Group. *Towards a tobacco free society.* Dublin: DoH, 2000.

EIGHT

Comparison: The Food Standards Agency

8.1 The Food Standards Agency is an independent food safety watchdog set up by the Food Standards Act 1999 to protect the public's health and consumer interests in relation to food. The Act sets out the Agency's main objective of protecting public health in relation to food and the functions that it will assume in pursuit of that aim, and gives the Agency the powers necessary to enable it to act in the consumer's interest at any stage in the food production and supply chain. The Act provides for the Agency's main organisational and accountability arrangements. In addition, it provides powers to establish a scheme for the notification of the results of tests for foodborne diseases.

What are the FSA's aims?

8.2 Between 2001 and 2006, the Agency's aims as stated on its web site are to:

- reduce foodborne illness by 20% by improving food safety right through the food chain (it is estimated by the FSA that there could be up to 4.5 million cases of food poisoning every year in the UK);
- help people to eat more healthily;
- promote honest and informative labelling to help consumers;
- promote best practice within the food industry;
- improve the enforcement of food law;
- earn people's trust by what it does and how it does it.

How is the FSA structured?

8.3 The Agency is led by a board that has been appointed to act in the public interest and not to represent particular sectors. Board members have a wide range of relevant skills and experience. The UK headquarters are in London, but the Agency also has national offices in Scotland, Wales and Northern Ireland. The Meat Hygiene Service is an executive agency of the FSA. The FSA is accountable to Parliament through health ministers, and to the devolved administrations in Scotland, Wales and Northern Ireland for its activities within their areas.

The FSA's responsibilities

8.4 The work of the FSA involves food safety across the whole of the food chain, including:

- food contaminants (defining tolerable levels, risk management and policy);
- food additives, contact materials, and novel foods (including safety assessment and surveillance);

- microbiological safety and food hygiene (including providing advice on the management of food borne outbreaks and prevention of food borne illness);
- inspection and enforcement action to protect consumers;
- local authority enforcement (developing policy, and auditing and improving enforcement);
- pesticides, veterinary medicines and animal feed (assessing food safety implications);
- food labelling and standards (developing policy, improving consumer choice and representing the UK in the EU);
- nutrition (providing advice and guidance on the nutritional composition of food, and providing information on a healthy, balanced diet, so as to promote and protect public health).

The FSA's powers and accountability

8.5 Although the FSA is a Government agency, it works at 'arm's length' from Government because it does not report to a specific minister and is free to publish any advice it issues. The FSA is accountable to Parliament through health ministers, and to the devolved administrations in Scotland, Wales and Northern Ireland for its activities within their areas.

8.6 The powers and function of the FSA are defined in the Food Standards Act 1999:

- **The Food Standards Agency** (**sections 1–5**), concerns the establishment of the FSA, its main objective and its main organisational arrangements including the establishment of advisory committees (more detailed provisions are contained in Schedules 1 and 2).
- **General functions in relation to food** (**sections 6–8**), confers on the FSA responsibility for developing food policy and advising Ministers and other public authorities, for advising consumers and other interested parties and for keeping abreast of developments relevant to its remit.
- **General functions in relation to animal feedingstuffs** (**section 9**), supplements the FSA's functions in relation to animal feed.
- **Observations with a view to acquiring information** (**sections 10–11**), gives the FSA functions in relation to surveillance and provides powers to enable it to carry them out.
- **Monitoring of enforcement action** (**sections 12–16**), gives the FSA a function of monitoring food and feedingstuffs law enforcement and provides powers to enable it to carry it out.
- **Other functions of the Agency** (**sections 17–21**), describes the Secretary of State and the devolved authorities' powers to delegate the making of emergency orders to the FSA, and the FSA's power to publish its advice.

- **General provisions relating to the functions of the Agency (sections 22–25)**, concerns certain considerations which the FSA must observe in carrying out its functions, provides for directions by ministers and the devolved authorities should the FSA fail to perform its duties, and allows for modification of enactments to allow disclosure of information to the FSA and publication by it.
- **Miscellaneous provisions (sections 26–35)**, sets out the functions no longer to be exercised by the Minister of Agriculture, Fisheries and Food, and the Department of Agriculture for Northern Ireland, and makes various provisions for consultation with other parts of Government or the devolved administrations on aspects of food safety.
- **Final provisions (sections 36–43).**

European dimension

8.7 There is considerable EU regulation in the area of food and food safety, currently managed by the European Commission and several scientific and regulatory committees.[9,10,11] The mission of the Directorate General for Health and Consumer Protection (known as the 'DG Sanco') is to implement the responsibilities entrusted to it by the treaty and derived legislation so as to ensure that a high level of human health and consumer protection is attained throughout the EU. DG Sanco also has prime regulatory responsibility for tobacco.

8.8 In January 2002, the EU agreed to establish the European Food Safety Authority (EFSA).[12] The measures introduced will reinforce existing consumer protection and should help re-establish consumer confidence in the food chain in Europe. The EFSA is an intrinsic part of a more strategic approach to food safety issues across the EU.

Budget

8.9 The net cost of the Westminster funded FSA (ie excluding Wales, Northern Ireland and Scotland) in 2000/1 was £83.7 million. The FSA also raises substantial funds (£48 million) through charges for the meat hygiene service. General food hygiene inspection is outside the remit of the FSA and is undertaken by the local authority's environmental health officers.

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9. DG Sanco, 'Food safety: from the farm to the fork', http://europa.eu.int/comm/food/index_en.html <Last accessed 13 November 2002>

10. DG Sanco, 'Scientific committees', http://europa.eu.int/comm/food/index_en.html <Last accessed 13 November 2002>

11. DG Sanco, 'Regulatory committees', http://europa.eu.int/comm/food/fs/rc/index_en.html <Last accessed 13 November 2002>

12. Regulation 2002/178/EC of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

13. Food Standards Agency. *Food Standards Agency annual report and accounts.* London: The Stationery Office, 2002.

8.10 The FSA divides up its expenditure according to the aims set by Government and Parliament.[13]

Table 1. FSA expenditure and income divided by aim.

Aim	**Expense** (thousands of pounds)	**Income** (thousands of pounds)	**Net** (thousands of pounds)
Aim 1: Measurably improve public confindence in the national food safety and standards arrangements	23,434	(397)	23,037
Aim 2: Reduce foodborne illness by 20% over the next 5 years including reducing salmonella in UK produced chickens on retail sale by at least 50% by the end of 2004/2005	38,910	(2,305)	36,605
Aim 3: To protect consumers through improved food safety and standards	69,447	(45,346)	24,101
Total	**131,791**	**(48,048)**	**83,743**

NINE

Comparison: The Medicines Control Agency

9.1 The MCA's primary objective is to safeguard public health by ensuring that all medicines on the UK market meet appropriate standards of safety, quality and efficacy. Safety aspects cover potential or actual harmful effects; quality relates to development and manufacture; and efficacy is a measure of the beneficial effect of the medicine on patients. The MCA achieves its objectives through:

- a system of licensing before the marketing of medicines;
- monitoring medicines and acting on safety concerns after they have been placed on the market;
- checking standards of pharmaceutical manufacture and wholesaling;
- enforcement of requirements;
- responsibility for medicines control policy;
- representing UK pharmaceutical regulatory interests internationally;
- publishing quality standards for drug substances through the *British Pharmacopoeia*.

History

9.2 The MCA was established in April 1989, taking over the duties of the Medicines Division of the Department of Health. It became an executive agency of the Department in July 1991 and was established as a trading fund on 1st April 1993 by the Medicines Control Agency Trading Fund Order 1993.

9.3 Effectively, a function previously managed within the Department of Health was moved out to become a separate and separately accountable body with autonomous funding. This could be a useful model for a tobacco and nicotine regulatory authority.

Advisory committees

9.4 There are several advisory committees that interact with the MCA. These are established under the Medicines Act 1968 or related regulations and many have functions that could find parallels in the regulation of tobacco.

- **Medicines Commission.** Twenty three members meet five times per year, to advise the Secretary of State on the application of the Medicines Act 1968. The Medicines Commission also advises on setting up other committees under the Act.

- **Committee on the Safety of Medicines (CSM).** This body provides advice on licensing of medicines to the Licensing Authority in conjunction with the MCA. The CSM is comprised of 34 members who are appointed by the UK's health ministers. Members include pharmacists, pharmacologists, toxicologists and physicians from a wide range of disciplines working in general practice, hospitals and universities across the UK. It also includes two lay members. The Committee meets fortnightly (except in August) and its secretariat is provided by the staff of the MCA.
- **The Advisory Board on the Registration of Homoeopathic Products (ABRHP)** gives advice with respect to safety and quality in relation to any homoeopathic medicinal product for human use.
- **Independent review Panel for Advertising.** The Medicines (Advertising and Monitoring of Advertising) Amendment Regulations 1999 came into force on 5 April of that year and complete the implementation of EU Directive 92/28/EEC. Regulation 13 and the Schedule contain a procedure for a review of the Health Minister's preliminary decision on whether an advertisement complies with the Medicines (Advertising) Regulations 1994, as amended ('the Regulations').
- **Veterinary Products Committee (VPC).** The VPC was established in 1970 under Section 4 of the Medicines Act 1968. Its terms of reference are to give advice with respect to safety, quality and efficacy in relation to the veterinary use of any substance.

European dimension

9.5 The control of medicines in the UK is primarily through the system of licensing and conditional exemptions from licensing laid down in EC legislation, the Medicines Act 1968 and in relevant subordinate legislation. Controls on medicines under the Medicines Act matched or in some cases exceeded those of existing European Directives and the UK played a major part in the development and revision of the EEC Directives in this area. European Community (EC) legislation now takes precedence over the Medicines Act, its Instruments and Orders, which are amended from time to time to align with new EC requirements.

9.6 The MCA plays an active role in negotiations and discussions in Europe and continues to represent the UK at key European meetings, such as Heads of National Regulatory Agencies, the Pharmaceutical Committee and the Committee for Proprietary Medicinal Products (CPMP). In addition, towards the end of 2000 the draft EU directive on good clinical practice and clinical trials reached a critical stage in its progress through the European legislative procedure.

9.7 The MCA continues to contribute to issues on which wider Department of Health and other government departments are in the lead. This has notably included the review of the General Product Safety Directive (that is the responsibility of the Department of Trade and Industry).

9.8 There is also a body operating at EU level; the European Agency for the Evaluation of Medicinal Products (EMEA), which is based in London. This body supervises the operation of the 'mutual recognition procedure' for authorisation of medicines, co-ordinates research, directly authorises biotechnology products and operates a pharmacovigilance network

throughout Europe. EMEA cooperates closely with the MCA – the current Chairman is Dr Keith Jones, who is also Chief Executive of the MCA. The MCA is one of the 'competent authorities' recognised by EMEA.

Budget

9.9 The budget for the MCA for 2000/1 was £38.4 million and it employed 436 people. The MCA raises its funds by charging for licensing and inspections (£18.3 million) and services (£12.4 million).

9.10 The budget for EMEA is EUR 65.9 million for 2001 (£40 million), and roughly equivalent to the budget for the UK regulator.

TEN

Options for a Tobacco and Nicotine Regulatory Authority

Objective

10.1 A tobacco and nicotine regulatory authority should have a clear objective:

> *… to reduce the overall burden of tobacco-related disease by contributing to a reduction in smoking prevalence and by regulating to reduce the harm caused to continuing nicotine users.*

Organisational form

10.2 There are several potential models that could be used:

- **Move existing functions to a new agency.** This approach was used with the formation of the Medicines Control Agency which advises the Secretary of State on the exercise of powers that were defined in earlier legislation.
- **Introduce new enabling legislation and powers to create a new agency.** This was how the Food Standards Agency was formed. The FSA has an independent role and powers conferred by its own legislation, the Food Standards Act, 1999. Tobacco could conceivably be included within the definition of food used in the Act (see Appendix 1).
- **Add tobacco regulation to the mandate of an existing body, amending its enabling legislation if necessary.** This could be the FSA or the MCA – or possibly a split between both.
- **Re-examination of existing legislation to create specific powers to regulate tobacco.** For example, the Consumer Protection Act 1987 or the newly adopted General Product Safety Regulations could be used to create a framework for tobacco regulation. The new agency could be created to advise the competent authorities defined in that legislation on the exercise of the relevant powers. The use of consumer protection legislation is discussed in question and answer form in Appendix 1.

Funding

10.3 Funding should, as far as possible, be raised from charges to the regulated industry – tobacco manufacturers, wholesalers, importers and exporters as appropriate. The MCA is entirely funded from external income, the FSA receives about 36% of its total funds from inspections and the Environment Agency earns 38% of its income from fees and levies.[14]

14. Environment Agency, 'Our income', http://www.environment-agency.gov.uk/aboutus/275155/234158/?version=1&lang=_e <Last accessed 13 November 2002>

Mandate for a tobacco and nicotine regulatory authority

10.4 The mandate of a tobacco and nicotine regulatory agency could be as follows:

Product regulation and consumer protection

- enforcing legislation in place – in concert with local enforcement agencies;
- establishing standards for novel tobacco or nicotine products;
- taking test cases on behalf of the Secretary of State where there is ambiguity or contention;
- managing disclosure of additives and publishing of public data;
- managing testing and disclosure of toxicity data for smoke and ingredients;
- formulating proposals for regulation of constituents of tobacco products and smoke;
- representing ministers on EU regulatory committees;
- conducting market surveillance;
- advising on warnings and consumer protection information required on packs;
- advising Secretary of State on risk communication to the public;
- challenging misleading risk communication;
- evaluating, approving or challenging health claims, whether explicit or implicit;

Non-tobacco nicotine products

- to advise the medicines 'licensing authority' (ie ministers) on the public health consequences of licensing particular non-tobacco nicotine products for sale in the UK. The authority would strike a 'concordat' with the MCA over their respective responsibilities.

Research and evidence clearing house

10.5 There is a clear need to have some continuity and experience with the science, law, economics and other policy aspects of tobacco. The authority could 'own' and develop expertise in this field on behalf of the government. For example, it could take responsibility for the following:

- Secretariat for Scientific Committee on Tobacco and Health;
- research and monitoring of wider tobacco control policies;
- gathering data on trends in tobacco use
  - prevalence and consumption
  - brand data
  - tobacco related disease trends
  - use of smuggled or budget cigarettes and switching to hand-rolling tobacco

- impact of new products
- impact of policy measures, including primary and secondary prevention intervention
- passive smoking exposure and indicators of responses.

10.6 Other functions that could be included in the mandate of a nicotine and tobacco regulatory authority are:

Marketing activity

- control and supervision of marketing activities of tobacco companies;
- enforcement of advertising legislation;
- developing regulations in response to technology developments;
- acting as a source of pressure for voluntary restraints on use of tobacco in films, magazines etc;
- contracting effective mass-media advertising campaigns and organising an education campaign;

Counter-marketing

- collating evidence and advise on campaign strategy;
- possibly 'owning' the campaign;
- commissioning evaluation;

Smoking cessation

- developing, disseminatimg, promoting and auditing implementation of best practice;
- offering support infrastructure;
- developing economic analysis and monitoring economic impacts;
- commissioning evaluation;

Passive smoking

- implementing the Approved Code of Practice on passive smoking at work;
- monitoring impact of voluntary agreements; and
- proposing legislation where necessary.

Economic and trade regulation

10.7 The UK tobacco industry is a duopoly and its two main companies earn super-normal profits. A large share of the UK cigarette market is also lost to contraband and counterfeit, and measures such as fiscal markings have been introduced to tackle these. There are a number of

economic and trade-related issues that could be managed by a tobacco regulator, including:

- smuggling;
- under-age sales;
- illegal sales;
- vending machines; and
- budget brands and price ranges in the marketplace.

ELEVEN

Conclusion

11.1 Having considered the issues discussed in this report, the College draws the following conclusions.

1. There are numerous and formidable regulatory challenges in the field of tobacco and nicotine. The approach taken to these challenges will be an important factor in determining the burden of disease caused by tobacco and nicotine use in the future.
2. The current almost-entirely unregulated position enjoyed by tobacco products and tobacco manufacturers should not be allowed to continue. Detailed consideration by Parliament concluded that some regulatory authority was essential to control and contain the tobacco industry and the harm caused by tobacco. The College has already argued the case for a Tobacco and Nicotine Regulatory Authority.
3. The Government has not strengthened its regulatory capacity since the Health Select Committee's report. The scientific capacity has actually been reduced. The practice of leaving tobacco policy and programme implementation to career civil servants who will often stay in post for less than two years will not be adequate to match the regulatory challenges posed by the evolving tobacco market.
4. The harm done by tobacco and nicotine use is to some extent controllable by influencing the design, blending and ingredients of tobacco products. Tobacco manufacturers will introduce new products with the aim of capturing a niche market for smokers concerned about health. Some smokeless tobacco products and pharmaceutical nicotine may offer substantial reductions in harm compared to smoking. Regulators cannot afford to ignore such developments – which are both public health threats and opportunities.
5. The regulatory arrangements for nicotine products apply the toughest controls to the least hazardous forms of delivery and apply minimal controls to cigarettes, the most hazardous form. A new authority should reconfigure this system so as to give the best outcome for public health.
6. We believe that the Government should act on the recommendations of the Health Select Committee and earlier advice of the College and establish a regulatory function for tobacco and nicotine outside the Department of Health. The function of a 'tobacco and nicotine regulatory authority' would be to advise the Secretary of State on how to exercise his regulatory powers, and to assume any responsibilities allocated to it in legislation.
7. Institutional precedents – notably the FSA – already exist. The FSA receives very substantial funding (£83 million p.a.) as well as fee income, yet the impact of food safety on public health is considerably less than the impact of tobacco.

8. Existing consumer protection legislation is available to give an authority the powers to act on behalf of ministers. Food and medicine regulation could also be applied to tobacco. However, the over-riding importance of tobacco in public health means that the Government should develop whatever legislation proves necessary at a later stage.

9. The body should be entirely funded by fees levied on the regulated industry – as is the case with the MCA and to some extent the FSA and Environment Agency. The authority should be established at national level without delay, with a European agency developed later. This is the approach adopted with food: the UK's Food Standards Agency has preceded the emerging European Food Safety Agency.

Appendix 1
Legal Q&A on a Tobacco and Nicotine Regulatory Authority

Given the existing and planned legislation, and experience of consumer protection measures, in the UK, what more could be done to regulate tobacco products, and how could an entity with the functions of the Tobacco and Nicotine Regulatory Authority be created?

Whilst it might be possible to apply the Medicines Act 1968 and Food Safety Act 1990 to tobacco, the Consumer Protection Act 1987 seems a more obvious and less contentious route to regulation. So long as the matter governs safety, that Act has fairly broad regulation-making powers, which should be broad enough to fulfil most European obligations. However, it might seem strange for a tobacco and nicotine regulatory authority to have to use the Consumer Protection Act (CPA) 1987 for tobacco when most of its uses are in relation to consumer products regulated by the Department of Trade and Industry, rather than public health matters. Specific tobacco legislation would be a more desirable basis for developing regulation in this area and would remove any doubt.

What new legislation would we need to achieve the aim of having a tobacco and nicotine regulatory authority with the mandate set out in the Commons Health Select Committee report and by the Royal College of Physicians?

There would need to be primary legislation establishing a tobacco and nicotine regulatory authority. Existing powers of secondary legislation might be able to be invoked by this authority recommending action to the relevant ministries, but equally it might be more desirable to create a new enabling power. The authority's role may well be simply one of supervising enforcement authorities. Such powers could be outlined in the legislation establishing the authority. If it were thought desirable for the authority to have enforcement powers itself these would have to be specified.

What obligations do the CPA 1987, and General Product Safety Regulations 1994 place on tobacco and nicotine manufacturers or vendors? Is there any existing body responsible for enforcing such obligations?

Obligations on manufacturers and vendors

The CPA 1987 Part II, s. 10, makes it an offence for a person to supply or undertake steps preparatory to the supply of defective consumer goods. Unfortunately the definition of consumer goods excluded tobacco from its scope (s. 10(7)(f)). Tobacco was defined as including any tobacco product within the meaning of the Tobacco Products Duty Act 1979 and any article or substance containing tobacco and intended for oral or nasal use.

In 1992 the EC adopted Directive 92/59/EC on general product safety, which also included a general safety requirement. This was implemented by the General Product Safety Regulations

S.I. 1994/2328, which, whilst not formally repealing s.10, disapplied it in most contexts. The important point for this discussion is that the definition of 'product' under these regulations is broader than the definition of consumer goods under the CPA 1987. Of most significance is the fact that tobacco is no longer excluded. The definition covers 'any product intended for consumers or likely to be used by consumers' (reg. 2(1)) and tobacco products seem to fall squarely within this definition. Thus there would seem to be no need to pass any measure to bring tobacco within the CPA's general safety requirement since this has effectively been done by the 1994 regulations.

Product safety

The main obligation is placed on producers only to place on the market products that are safe (reg.7). A safe product is,

> *any product, which under normal or reasonably foreseeable conditions of use, including duration, does not present any risk or only the minimum risks compatible with the product's use, considered as acceptable and consistent with a high level of protection for the safety and health of persons, taking into account in particular –*
>
> *a) the characteristics of the product, including its composition, packaging, instructions for assembly and maintenance;*
>
> *b) the effect on other products, where it is reasonably foreseeable that it will be used with other products.*

Whilst this would not seem to provide the means to condemn tobacco products as a class, given that the risk only has to be the minimum compatible with the product's use, nevertheless the risk must be an acceptable one consistent with a high level of protection. The wording of the definition seems rather strict: 'does not present any risk or only minimum risks compatible with product's use'.

The question of what constitutes minimum risk is a thorny one. There have been recent product innovations that may reduce risk, but it is extremely difficult to measure with confidence. There is also the problem that it may be possible to make genuinely 'safer' products but such products may differ so much from the existing product line that consumers would not find them acceptable.

Warnings

As packaging can be taken into account it might be possible to argue that inadequate warnings render a product unsafe, but this is unlikely, especially given the statutory prescriptions on warnings. Although one might find a court reluctant to condemn a product which complies with regulations this is not an automatic defence. Reg. 10(1) merely provides that where a product conforms to specific rules of UK law laying down health and safety requirements there shall be a presumption that the product is safe, until the contrary is proved. However, reg. 10(2) states assessment of conformity with the general safety requirement will take into account (in what is not expressly stated to be a hierarchy, but probably should be treated as such):

(i) UK voluntary standards giving effect to a European standard;

(ii) Community technical specifications and then if none of them exist;

(iii) UK standards, codes of good practice or the state of art and technology and finally;

(iv) the safety which consumers may reasonably expect.

The general safety requirement found in reg. 7 is fleshed out for producers in reg. 8. These may be of some use in connection with tobacco. Reg. 8(1)(a) concerns risks which are not immediately obvious without adequate warnings. Consumers must be provided with relevant information to enable them to assess inherent risks and to take precautions against them. Thus this would seem to require tobacco manufacturers to have clean hands as regards disclosing potential dangers. Of course it may not always be possible to take precautions against inherent risks, save by not using the product, but disclosure of risks would seem to be adequate.

Research into risks

Reg. 8(b) is also of interest because it requires producers to adopt measures commensurate with the characteristics of their products to enable them to be informed of the risks the products might present. This is normally seen as requiring a strategy to be in place to learn about problems presented by the product in the market place. However, this can also be read as requiring the industry to have a research strategy adequate to learn more about the risks posed by its products. One problem with reg. 8 is that there is no specific offence for breaching it, the offence is for breach of reg. 7, the general safety requirement. It might of course be possible to argue that failure to undertake the activities required by reg. 8 would make the product less safe than it otherwise might be and therefore constitute evidence of a breach of the general safety requirement, but this is by no means self-evident, especially where the problem is lack of a strategy to be informed of risks.

Under reg. 9 distributors are under an obligation to act with due care to ensure compliance with the general safety requirement. In particular reg. 9(a) requires that they shall not supply products they know or should have presumed to be dangerous. Reg. 9(b) requires that within the limit of their activities they participate in the monitoring of products, particularly by passing on information and co-operating in action taken to avoid those risks. Breach of reg. 9(a) is an offence.

Enforcement powers

The 1994 Regulations share the same enforcement powers as the CPA 1987 (reg. 11). Some of these are granted to the Secretary of State and are exercised by the Consumer Safety Unit of the Department of Trade and Industry. In practice these powers are used very sparingly. Prohibition notices can be served on individuals by the Secretary of State to prevent them from supplying the goods specified in the notice (s. 13(1)(a)). They are used for rogue products and only a handful of such notices have been issued. A notice to warn issued by the Secretary of State can require a person to publish a warning about goods considered to be unsafe (s. 13(1)(b)). This power has never been used and is unlikely to be used as the procedures are very cumbersome.

The majority of enforcement action is taken by trading standards officers at the local level. Their main weapon is the suspension notice (s. 14) which can prohibit a person from taking a variety of measures related to the sale of the product for a period of up to six months. They can also apply to the magistrates' court for a forfeiture order (s. 16). A major impediment to the effective use of these powers is the requirement that authorities pay compensation if it turns out their suspicions were not well founded (s. 14(7)).

What are the powers to regulate tobacco and nicotine available in the CPA 1987 and General Product Safety Regulations 1994?

The CPA 1987 provides specific enabling powers to permit the enactment of safety regulations. These powers are broader than that act's general safety requirement, for it applies to all goods rather than just consumer goods, and whilst some products are excluded these do not include tobacco. One of the exclusions does relate to controlled drugs and licensed medicinal products (s. 11(7)(d)) and so if tobacco or nicotine was deemed to fall under the medicinal products regime the regulation making powers in the CPA 1987 would not be available.

The regulation making power in s. 11(1) of CPA 1987 is very broad and covers securing that the goods are safe, preventing products from falling into the hands of persons for whom they would be unsafe, and making sure that appropriate information is, and inappropriate information is not, provided. The section is thus very wide-ranging and would seem to be broad enough to do many of the things one might wish to do, ie ban constituents/toxins/additives or demand reductions in them, set upper limits to emissions, demand product modifications, demand that cigarettes meet common performance standard on constituents or by-products, demand changes to cigarette paper/filter etc. To this extent the advice of the Government solicitor seems correct. S. 11(1) is developed in s. 11(2) where certain specific provisions that safety regulations may contain are listed. It should be borne in mind that this list is expressly stated to be without prejudice to subsection (1), but that the overall objective listed in s.11(1) must guide the content of the regulations, ie safety must be to the fore. One might imagine some debate as to whether, for example, passive smoking was a safety or a discomfort issue.

There does not seem to be any express power which would require the licensing of manufacturers and importers. The rules on approvals seem to relate to the goods rather than the person controlling them. Indeed the overarching power in s. 11(1) seems to be related to the goods, and so controls on who can deal in the goods might well be deemed to fall outside its scope.

The safety regulations themselves cannot provide that any contravention of them will be an offence (s. 11(4)), but s. 12 provides for various offences against safety regulations.

What are the implications of the exemption of tobacco from the consumer safety part of the CPA 1987 at s. 10(7)(f) – and, by extension, what would be the implications and feasibility of amending the Act to remove this?

The exemption of tobacco in s. 10(7)(f) of the CPA 1987 would seem to be of little relevance now. It had the effect of not making the general safety requirement in s. 10 applicable to

tobacco, but this has now been superseded by general safety requirements in the General Product Safety Regulations, which do not exclude tobacco. The other powers in the CPA 1987 relating to safety refer to 'goods', which has a broader meaning than 'consumer goods' and would include tobacco, unless tobacco was deemed to be a licensed medicinal product.

What are the implications of the section 3(c) (application and revocation) of the 1994 regulations? Given that tobacco is to be regulated under the new tobacco product directive (and previously under 90/239/EEC on tar yields, and 89/622/EEC and 43/92/EC on labelling) would the directive mean these regulations did not apply to tobacco?

The relationship between the general safety requirement and specific sectoral directives is problematic. The best approach from a consumer protection point would be to have both sectoral rules and the general safety requirement apply. This is clearly not the approach of the General Product Safety Directive. At the other extreme one might wish the general safety rules to be disapplied whenever there were any sectoral safety rules in directives that were intended to be total harmonisation directives dealing with all safety aspects. Slightly less extreme would be to argue that if sectoral rules covered safety then the general product safety directive only applied as regards its post-marketing notification obligations. In fact the United Kingdom seems to have adopted the sensible approach of retaining the controls afforded by the general safety requirement whenever the specialist legislation does not cover a specific aspect of safety. This seems to be the effect of the Regulations, for although reg. 3(c) excludes any product for which there are specific community rules, this exclusion only applies where the specific provisions govern all safety aspects of the product. Furthermore reg. 4 makes it clear that the regulations do apply where the product is subject to Community law provisions in so far as those provisions do not make specific provision governing an aspect of the safety of the product. However, the matter is not entirely free of ambiguity. There may still be some situations where producers may try to argue that all safety aspects are covered by the Community law and the authorities are then forced to show that some novel or distinct aspect has not been included in the specific EC law, even if it had been intended to be a total harmonisation directive.

It should be noted that the General Product Safety Directive is in the process of being revised. There has not been time to make a detailed study of the proposed changes, but of interest is the fact that one issue to be reformed is the relationship between sectoral legislation and the general safety requirement. The procedure for assessing conformity is also to be reworked with it being likely that a greater role will be given to standards implementing European standards.

Going beyond the issue of exclusion from the general safety requirement where sectoral directives exist, it should be noted that there is a more general issue concerning the relationship between EC internal market law and domestic law. As confirmed by the tobacco advertising decision internal market law is an area of exclusive Community competence. This means that, at least once the Community has enacted laws in this area, member states cannot regulate, except as provided for by EC laws. This is an important issue, which may prevent national activity in areas such as tobacco products that have been regulated at the EC level and needs exploring in more detail. In particular art. 13(2) of the Tobacco Products Directive needs consideration because it does seem to permit member states to keep or introduce more

stringent rules, but only in so far as they do not prejudice the rules laid down in the Directive. The scope this gives member states to derogate from the directive needs to be assessed.

What are the powers to regulate tobacco and nicotine available in the Medicines Act 1968?

If tobacco (or nicotine) fall within the definition of a 'medicinal product' then they would be subjected to the licensing regime of the Medicines Act 1968. To fall within this definition they would have to fulfil a 'medicinal purpose' and the most relevant test would seem to be that found in s. 130(2)(e) of 'otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way'.

There does not seem to be any express exclusion for tobacco. In deciding whether tobacco products fall within this definition some assistance might be gleaned from the US Supreme Court case of *Food and Drug Administration v Brown & Williamson* where the Food and Drug Administration (FDA) was denied authority. Some aspects of this case turn upon particular US issues. Under the US legislation 'drugs' are defined to include 'articles (other than food) intended to affect the structure or any function of the body' and a 'device' is 'an instrument, apparatus, implement, machine, contrivance … or other similar or related article… intended to affect the structure or any function of the body'. The FDA considered nicotine a drug, and cigarettes and smokeless tobacco products 'drug delivery devices'. The issue of intent does not seem to be a factor in the UK. Moreover the majority in Supreme Court were clearly influenced by the FDA having previously denied authority and Congress having created a special regime to regulate tobacco products. However, what is perhaps of most interest is the view of the majority that because of the need for any approved drug device to have a 'reasonable assurance of safety and effectiveness' the result would have to be a ban and that it could not have been intended to give a regulatory agency the power to ban a product which is so central to American society. The FDA and the minority argued that they would have power to take less drastic steps than banning the product, particularly as they could take into account the harm caused from the sudden withdrawal of the product.

The wording of the UK Medicines Act 1968 would appear to be more favourable to tobacco regulation. The concepts of 'safety', 'quality' and 'efficacy' that underpin the regulation of medicine are not easily applied to tobacco, and these are stated to be the three factors the licensing authority shall take into consideration. However, they are simply that – factors to be taken into consideration. It seems quite striking that in the US there was little dispute that nicotine and tobacco products fell within the literal interpretation of drug or device. Thus it would seem to be feasible to argue that tobacco products should be regulated under the medicines regime. Indeed the irony has been noted that whilst tobacco is not regulated in such a manner, many of the products (nicotine replacement treatment) used to treat the effects of nicotine addiction do have to go through the medicine licensing process. However, one suspects there will also be a deal of popular resistance to tobacco being equated with a drug and it must also be recognised that tobacco would then fall outside the regulation-making powers of the CPA 1987 (s. 11(7)(d)). Furthermore one might wonder whether a licensing regime was an adequate means of implementing Community obligations. This matter would have to be looked into further if this avenue was to be seriously explored.

What are the powers to regulate tobacco and nicotine under the Food Safety Act 1990?

The Food Safety Act 1990 might cover tobacco products. There is certainly no express exclusion for tobacco (again there is an exclusion for licensed medicinal products, unless excepted by Ministerial order). Food is said to include 'articles and substances of no nutritional value which are used for human consumption' (s. 1(1)(b)). It would seem that tobacco products fall within the definition of articles or substances (s. 53(1)). The only debate might be whether they are consumed. If this was seen as being a crucial point then more research could be undertaken.

There are wide ranging regulation-making powers under s. 16 and schedule 1 of the 1990 Act. These include regulation on composition, governing processes and treatment in the preparation of food, regulating the labelling, marking, presentation and advertising. There is also a general power for regulations to secure that food complies with food safety requirements, the interests of public health or to protect or promote the interests of consumers. S. 25 also allows the minister to require persons to furnish specified information about the food.

Could the new tobacco product directive be introduced as regulations under the CPA s. 11?

The tar yield (90/239/EEC) and labelling (89/622/EEC etc) directives are implemented in regulations under the CPA, and the new directive 2001/37/EC is a consolidation of these directives with a few new but related provisions. It will be obvious from the above that there would seem to be a sufficient basis in s. 11 of CPA 1987 to use this to implement most safety measures relating to tobacco. However a future project might take the directive and assess whether every provision can be validly adopted on this basis. The preference would clearly be for specific enabling powers geared to tobacco and supervised by a tobacco and nicotine regulatory authority.

For products other than tobacco, what kind of institutional arrangements have been used to enforce the CPA 1987 and GPS Regulations 1994?

As outlined above the main enforcement authorities are the local government trading standards departments. Central government, through the Consumer Safety Unit of the Department of Trade and Industry, does have some enforcement powers but uses these infrequently and tends to act more as a supervisory body, handling data collection and the development of any regulations or standards.

Appendix 2
Review of European Union tobacco regulation

Product regulation and consumer protection

Though the 1989 labelling directive (89/622/EEC) was welcomed at the time, it normalised warning labels that are too small, with weak messages using contrasting colours that can be almost impossible to read. Although a member state can impose more substantial warnings on its domestic manufacturers, it cannot block the import of products conforming to this directive.

The 1992 update to labelling directive (92/41/EC) provided new warnings and banned oral tobacco outside Sweden. This form of tobacco is substantially lower risk than cigarettes and is one reason why there is a lower cancer rate in Sweden.

The 1990 'tar' directive (90/239/EEC) wrote into law and established as a legitimate public health measure the strategy of reducing tar yields – and lending credibility to the concept of light and mild branding. This approach is now discredited in public health terms – however, this mistake was perpetuated in Article 3 and 5 of 2001/37/EC (the new directive superseding 90/239/EEC).

The new tobacco product directive (2001/37/EC) contains some good provisions (larger and bolder warning labels, ingredients disclosure, removal of misleading branding, review and update provisions) and some bad provisions (tar reduction, labelling with tar yield numbers). This is subject to challenge by tobacco companies (see British American Tobacco release, 24 August 2001).

Tobacco advertising

The 1989 'Television without frontiers' directive (89/552/EEC) banned advertising on TV but did not deal with the dominant form of TV advertising – televised sponsored events. The 1998 tobacco advertising directive (98/43/EC) was struck down by the European Court of Justice in October 2000 on account of its legal base (Case C-376/98) – the court argued that the Directive must contribute to 'eliminating appreciable distortions of competition' and 'eliminating obstacles to the free movement of goods and to the freedom to provide services'. The Court found the directive failed these tests.

In 2001, the Commission proposed a new advertising directive (COM/2001/0283 final) and this is formulated to act within the Commission's conservative view of the narrow boundaries of EU competence established by the treaty as interpreted by the European Court of Justice. The directive covers four areas of cross-border advertising (printed publications, Internet, radio and sponsorship), but does not include indirect advertising and will be easily circumvented by modern promotional techniques or moving promotional activity – such as

sports sponsorship – outside the EU. The German government has already threatened to challenge this directive if it has the effect of banning tobacco advertising in newspapers whose main circulation is within Germany.

Tobacco subsidies and public health funding

The European Union provides almost €1 billion to tobacco farmers through the Common Agricultural Policy (98/2848/EC). In contrast, expenditure on tobacco and public health is about 2-3% of this – the 'Europe Against Cancer' programme (see 646/96/EC) and the Tobacco Fund (see Regulation 2000/1648/EC which elaborates the operation of the fund established in Article 13 of 92/2075/EC – the tobacco subsidy regime).

Excise duties

The EU has applied limits governing the structure of tobacco duties (see directives 92/79/EEC on cigarettes, 92/80/EEC on products other than cigarettes and 95/59/EC). These may have had some effect in raising minimum duties, but their prime purpose is to stop the use of the excise tax system acting as a protectionist barrier to trade. A new proposal to restructure and raise minimum excise duties (COM/2001/0133 final) has been proposed by the Commission.

Weakness of health and consumer protection in the treaty

The fundamental weakness in EU tobacco policy is that the treaty article on public health (art. 152) does not allow binding EU legislation – directives or regulations. Public health legislation on tobacco has been shoehorned in as 'single market' legislation under art. 95. Consumer protection legislation is similarly constrained: art. 153 on consumer protection requires the use of art. 95 on the single market.

Dominance of free trade

Art. 95 of the treaty establishes the single market and does require 'a high level of health and consumer protection'. However, the ECJ emphasised that the primary purpose must be to remove barriers to trade.

A particular concern is the possible use of treaty provisions on the free movement of goods and services (art. 28) to undo national public health legislation. For example, national advertising legislation could be challenged as a barrier to entry.

Art. 30 allows a public health defence but the burden of proof is on the public health authority to show the measure is 'proportionate'; 'such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States'.

This is not hypothetical – there are developments in this area:

- Complaints to the Commission about the French 'Loi Evan' and other national legislation.

- Swedish alcohol case (Case C-405/98) (a challenge to Sweden's ban on alcohol legislation). This appears to leave the matter to the Swedish courts to decide if the ban is justified in health terms.
- A potential Commission challenge to UK Customs over border controls designed to stop cross-Channel bootlegging. This could open the way for increased bootlegging and make the UK's tax policy harder to defend.

International negotiating positions: the EU forces the lowest common denominator

The position of the EU in the Framework Convention on Tobacco Control (FCTC) negotiations has been obstructive. For two reasons, the EU tends to drag its position down to the level of the least progressive member state. First, the member states *must* negotiate common EU positions where there is EU legislation in force. In the FCTC the EU has simply put forward positions that are already agreed within the EU, though it could agree more progressive positions if member states could agree them. Second, art. 300 of the treaty requires co-ordinated positions, even where there is no Community competence. In both cases, the EU negotiators have been drawn down to a position acceptable to the least progressive country – Germany.