The letter England's Minister for Public Health should now write

written by Clive Bates | 2 July 2015



> The letter the minister should write, not one she did….

If I was England's Minister for Public Health, this is the letter I would write today, just as the proposed UK implementation of the EU Tobacco Product Directive is announced for consultation. The EU directive may be an anti-scientific, unprincipled and unlawful mess, but there is still plenty that can be done in the UK or England. One thing would be to have all the agencies involved in delivering tobacco harm reduction / e-cigarette policy aligned and maximising the opportunity. This is the letter that would do that:

Minister for Public Health
Department of Health
Richmond House
Whitehall, London

Sir Michael Rawlins, Chair, Medicines and Healthcare Products Regulatory Agency
Professor David Haslam CBE, Chair, National Institute for Clinical and Healthcare Excellence
Professor David Heymann CBE, Chair, Public Health England
Dame Sally Davies DBE, Chief Medical Officer for England
Professor John Ashton CBE, Chair and President, Faculty of Public Health

Dear colleagues

Alignment of agencies and partners in delivery of tobacco harm reduction

As we advance towards implementation of the EU Tobacco Products Directive, including new regulations for e-cigarettes and other electronic nicotine delivery systems to be introduced in May 2016 under Article 20 of the Tobacco Products Directive, I thought this would be a good time to set out what the government expects from the bodies involved in delivering this important opportunity for public health.

Overall we expect our agencies and partners to work together towards maximising the public health opportunity, while addressing any residual risks in a way that is proportionate and evidence based, and with awareness of the potential for unintended consequences – primarily arising from protecting the cigarette trade from competition from products that offer nicotine users far lower risks than cigarette smoking.

1. MHRA

1.1 Building trust and credibility. As the proposed competent authority and therefore responsible for the protection of consumers, MHRA needs to work hard to earn the trust and confidence of those whose interests it is there to protect. The MHRA lost trust after its 2010 attempt (*Public consultation MLX 364: The regulation of nicotine containing products*) to classify all e-cigarettes as medicines, require marketing authorisation and so remove them all products from the market in 21 days. The strong response from around 1000 consumers was so compelling that was abandoned and the MHRA asked to think again. While it may have been a mistake to ask a medicine regulator whether a consumer product should be regulated as a medicine, that should not have been justified undertaking the rethink behind closed doors with insiders detached from the consumer experience and with negligible engagement with the consumers who had actually precipitated the rethink. We were advised by MHRA to reiterate its original policy and on 12 June 2013 we again announced our intention to regulate the products as medicines – only to have this idea defeated again by consumers in the European Parliament four months later. The appointment of the MHRA as competent authority will convince many that we are acting in bad faith and simply trying to re-introduce medical licensing by the back door and over the

heads of consumers. I expect the Agency to take concrete steps to engage consumers, to learn from their insights and to recognise the strength of their view: *nothing about me without me*. I hope you will convene a consumer panel, appoint a consumer champion or something similar to bring consumer insight to your work and to explain your approach more considerately than MHRA has done in the past. I look forward to receiving your proposals.

1.2 The importance of appeal and the challenge of pleasure. If we regulate to have the safest and most precisely calibrated nicotine delivery devices, but smokers do not wish to use them then we will not have achieved anything for public health. For this to work for public health, smokers must find them appealing as an alternative to smoking. This market is quite different to the ones that the MHRA is more familiar with regulating – it involves pleasure, some frivolity, branding, a huge diversity of products and niches, rapid consumer-driven innovation and consumers who do not consider themselves to be patients or in treatment. Many of these characteristics will be unfamiliar to the Agency and its assessors. To succeed we will need the Agency to understand and assimilate the basic value proposition of these products as alternatives to smoking and to ensure that regulation does not damage these products as competitors to smoking. The last thing this government wants from MHRA is regulatory protections for the cigarette trade and excessive regulatory barriers to entry to the e-cigarette market that will mean only tobacco companies can compete in it.

1.3 Pragmatic implementation of bad law. As you may be aware, my predecessor was not especially focussed on this section of the directive, and appears to have thought e-cigarettes had 'fallen out' of the text when she agreed to earlier drafts without due scrutiny in Parliament. While our officials should have avoided agreeing yet more bad law that feeds the Brexit tendency, we have the directive we have unless Totally Wicked do us all a favour and succeed in striking it down. Nevertheless, I would like MHRA to approach this pragmatically, and to recognise the many deficiencies in Article 20 of the Directive. The government will always uphold the law, but I would like MHRA to exploit the flexibilities and ambiguities in the language of the directive and implementing regulations to the greatest extent possible to create a liberal light touch regime for regulating these products. The approach to regulation should be proportional to risk; evidence based; and non-discriminatory – recognising these products compete with cigarettes and heat-not-burn tobacco products. So far we have

been unable to find much going wrong with these products that is not quickly corrected by market forces, through which consumers are determining what products are effective. The figures collected by ASH for adults and young people and in the Smoking Toolkit suggest much is going well and that e-cigarette use is overwhelming concentrated in adults and smokers. Given the the TPD is unlikely to improve on the current situation, it is important therefore that new EU regulation does as little damage as possible, building trust and confidence in the products, but not reshaping the market or substituting the government's opinion of what is a good product for the preferences of consumers.

2. NICE

2.1 Bring guidance up to date. The pace of innovation in the market, and in policy and regulation, means that the *NICE guidelines [PH45] Smoking tobacco harm reduction approaches* are now out of date and creating counterproductive confusion, hostility or excessive caution in clinical practice. Understandable concerns about 'unlicensed products' have not hardened into material risks to consumers, while it appears that thousands of users have found these products to be successful alternatives to smoking. We also have good examples of creative approaches to e-cigarettes in Stop Smoking Services and these products hold out considerable promise in some of most challenging settings. There is also evidence that these products are more effective than licensed products, at least in the over-the-counter setting:

> *People attempting to quit smoking without professional help are approximately 60% more likely to report succeeding if they use e-cigarettes than if they use willpower alone or over-the-counter nicotine replacement therapies*

This finding rather challenges the implicit assumption that licensed products will inevitably be more effective, and we need to recognise that in revised guidelines.

2.2 Practical guidelines for real world settings. We also need to find a way for Stop Smoking Services to embrace the technologies that smokers wish to use, or they will become less relevant, more expensive and in continued decline. The rise of vaper products, and the evident consumer preference to use them, should be recognised as a great opportunity for prevention of ill-health in all settings, exactly as envisaged by the NHS Chief Executive, who believes we should be

"getting serious about prevention". I believe updated NICE guidance could be usefully informed and harmonised with the work of National Centre for Smoking Cessation and Training, which has taken an excellent pro-active stance in its E-cigarette briefing for Stop Smoking Services. Guidelines should address the needs of primary care, hospital staff and those working in mental health institutions, for example. A more innovative approach could also include evidence-based officially sanctioned guidance for use by vendors and in retail settings, including pharmacies, convenience stores, vape shops and on the internet – recognising that these products may appeal to smokers who do not define themselves as patients and who would not ordinarily engage with health services for advice.

3. Public Health England

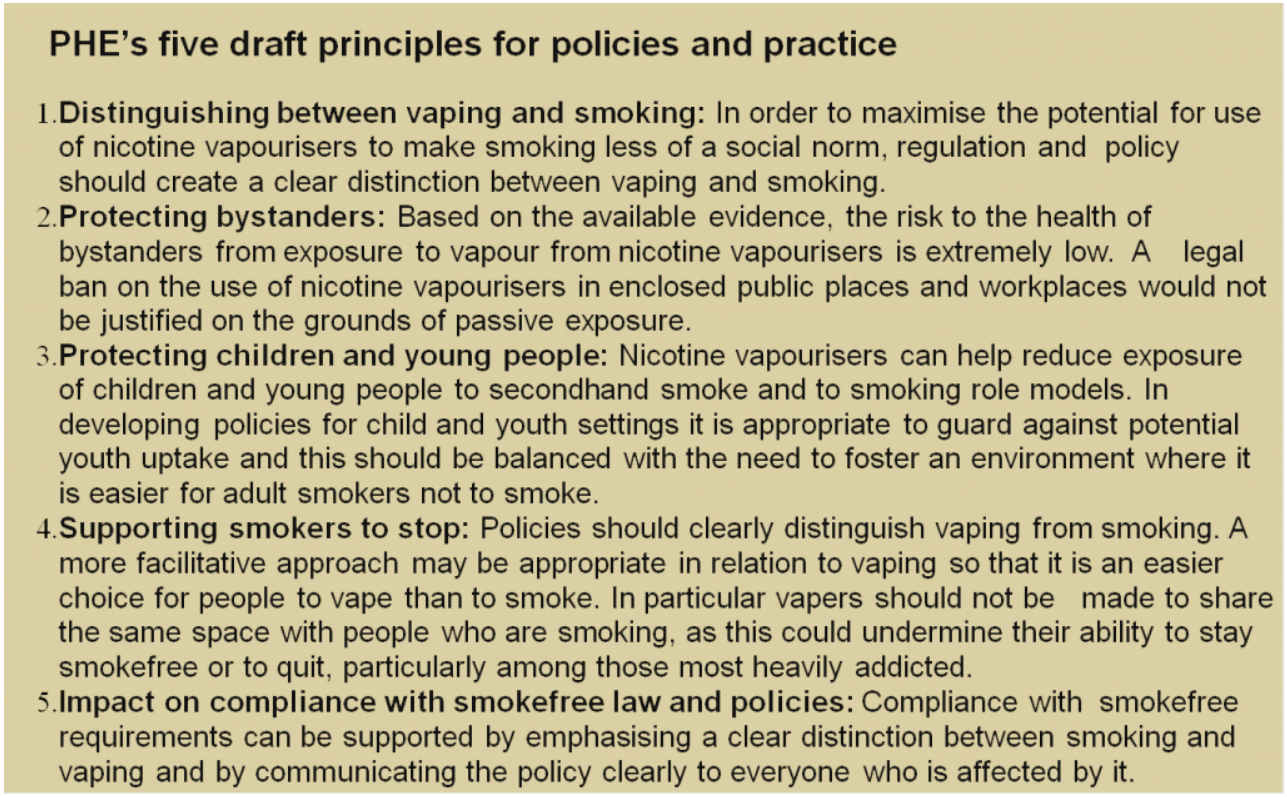
3.1 Addressing misperceptions of risk. The government is dismayed that the Smoking Toolkit Survey 29 April 2015 show that only a minority of current smokers (44%) believe e-cigarettes are less harmful than cigarettes. A different study undertaken by ASH show that few adults (17%) understand e-cigarettes to be *a lot less risky* than smoking. However, the UK's foremost experts have expressed the relative risk as follows:

> *From analysis of the constituents of e-cigarette vapour, e-cigarette use from popular brands can be expected to be at least 20 times safer (and probably considerably more so) than smoking tobacco cigarettes in terms of long-term health risk*

There is clearly a large and harmful disparity between the expert understanding of relative risk and the at-risk public's perception of relative risk. I would like PHE to assume the responsibility for defining, measuring and correcting this disparity, so that the public over time has perceptions of risk that are better aligned with reality, and people are therefore able to make better informed health-related decisions.

3.2 Embracing e-cigarettes in public health campaigns. There is no reason to exclude e-cigarettes from public health campaigns such as Stoptober, Change 4 Life, No Smoking Day or NHS Smokefree. Where we have control or influence I would like to ensure that the government is not missing opportunities to provide sound advice and motivation to smokers on e-cigarettes.

3.3 Policy implementation. We expect PHE to provide well formulated advice and guidance that is of practical value to practitioners, within a framework agreed by ministers. One such example, is the principles for managing vaping in public places – a model of reasoned and reasonable advice:



PHE's five draft principles for policies and practice

1. **Distinguishing between vaping and smoking:** In order to maximise the potential for use of nicotine vapourisers to make smoking less of a social norm, regulation and policy should create a clear distinction between vaping and smoking.
2. **Protecting bystanders:** Based on the available evidence, the risk to the health of bystanders from exposure to vapour from nicotine vapourisers is extremely low. A legal ban on the use of nicotine vapourisers in enclosed public places and workplaces would not be justified on the grounds of passive exposure.
3. **Protecting children and young people:** Nicotine vapourisers can help reduce exposure of children and young people to secondhand smoke and to smoking role models. In developing policies for child and youth settings it is appropriate to guard against potential youth uptake and this should be balanced with the need to foster an environment where it is easier for adult smokers not to smoke.
4. **Supporting smokers to stop:** Policies should clearly distinguish vaping from smoking. A more facilitative approach may be appropriate in relation to vaping so that it is an easier choice for people to vape than to smoke. In particular vapers should not be made to share the same space with people who are smoking, as this could undermine their ability to stay smokefree or to quit, particularly among those most heavily addicted.
5. **Impact on compliance with smokefree law and policies:** Compliance with smokefree requirements can be supported by emphasising a clear distinction between smoking and vaping and by communicating the policy clearly to everyone who is affected by it.

4. Chief Medical Officer for England

4.1 Trust and credibility. We welcome the advice of the CMO on a range of matters, provided this is dispassionate, scientifically reasoned, reality-based and within her areas of competence. On the subject of e-cigarettes, the CMO has not always met these expectations. I welcome advice from the CMO, but in future I would like officials to ensure that advice that reaches ministers and the public is rigorously evidence-based and grounded in what is actually happening in the market place and among users, not on hypothetical concerns for which no evidence exists.

5. Faculty of Public Health

5.1 Quality of advice. We are increasingly frustrated by advice and lobbying coming from the Faculty of Public Health. When one of the UK's leading specialists on tobacco policy and smoking cessation is moved to describe

prominent representatives of the Faculty of Public Health in the following terms, we should acknowledge a problem:

> *Public health activists and bodies who are not experts in the field of tobacco control, who misunderstand what is relatively complex evidence and present their misunderstandings to the wider community*

5.2 Attitude to the public. The Faculty appears to see is role as attacking and antagonising the very people we are trying to help, sometimes in a torrent of abuse, sometimes by implying they are 'astro-turf' and misrepresenting them, always without any apparent understanding of vapers and vaping, and without actually engaging with its critics other than through the safety of its supporters in the media. I wish to make it clear that my department has no truck with this attitude. If there is evidence that vapers are part of an internet based conspiracy please produce it, or stop making these accusations. For the record, we expect professionals in public health to abide by the seven principles of the UK Public Health Register, Code of Conduct:

1. Make the health and protection of the public your prime concern
2. Maintain high standards of professional and personal conduct
3. Be honest and trustworthy
4. Protect confidentiality
5. Respect the dignity of individuals and treat everyone fairly
6. Know the limits of your competence and act within them
7. Cooperate with the teams with which you work and interact

5.3. Authoritative body for consultation? While I recognise that FPH is a registered charity and independent of government, it does seek "*to act as an authoritative body for the purpose of consultation in matters of educational or public interest concerning public health*". That charitable purpose would be valuable providing it takes a rigorous approach to evidence and conducted itself professionally. Until then, we will seek authoritative e-cigarette advice from the Royal College of Physicians itself, and review our grant funding accordingly.

Summary

The government wishes to exploit to the greatest extent possible the opportunity to prevent ill-health through the new vapour technologies. This offers the

prospect of a market-based approach to one of the most serious public health problems – at no cost to the taxpayer and without consuming scarce NHS or local authority resources. To do this, we need all the delivery agencies to take a coherent, innovative and open minded approach to the challenges. I do not want to see the entrenched risk-aversion of public bodies have the effect of increasing risks to the public, by denying or compromising their access to safe and attractive products as alternatives to smoking.

Yours sincerely,

Clive Bates

***NOT* the real Minister for Public Health**