



Rt. Hon. David Cameron MP
The Prime Minister
10 Downing Street
London
SW1A 2AA

16 May 2016

Dear Prime Minister

Vaping and the Tobacco Products Directive - follow up to PMQs 11 May 2016

We write as consumer and public health advocates in favour of vaping for reasons of consumer choice and public health. We welcome your commitment at PMQs to look into whether vapour technology is appropriately regulated under the Tobacco Products Directive (2014/40/EC Article 20) and to respond to the question from your Conservative colleague, Anne Main MP.

In our view, this regulatory intervention has been one of the most serious health policy failures of recent times, from which many lessons should be drawn. The main issue is that a promising emerging technology has been treated as if it poses a mortal threat rather than creating a major health opportunity. It is now subject to careless and largely pointless over-regulation using the most inflexible instrument, an EU directive, which will be difficult to adjust to accommodate reality. Regulation has been driven by misguided hostility among public health activists, regrettably including the Chief Medical Officer.

To assist with your response to Anne Main MP, we would like to provide this briefing and some recommendations about what can be done, given the EU directive was signed into law in May 2014 and the UK is obliged to comply.

These are the key issues in the Tobacco Products Directive (2014/40/EU) as they apply to vaping, primarily the measure in Article 20:

The EU directive is extremely poor legislation based on confused policy. The Directive is a terrible mess of *ad hoc* restrictions that serve no purpose, huge and repetitively redundant bureaucratic burdens, great costs and numerous unjustified restrictions on the free movement of goods, which was the ostensible purpose and legal base of the directive. The directive has the effect of protecting an extremely harmful incumbent (cigarettes) while throttling a disruptive and highly beneficial entrant. We attach a more detailed critique of the directive. [1]

The EU directive will do much harm but no good. It is likely that the impacts of the Directive on vaping will be dominated by major unintended consequences. The Department of Health impact assessment cannot identify, let alone quantify, any material benefits. However, it shows first signs of government candour about the risks that arise from making vaping more expensive, less accessible, more boring, less appealing through clumsy regulation. To the

extent that poor regulation reduces the appeal of vaping products relative to smoking, it protects the cigarette trade, supports continued smoking and promotes black market activity. We have written to the Department outlining our concerns, and we attach this letter [2].

An EU directive is the wrong way to regulate a new and disruptive technology. The use of a legal instrument as inflexible as a European Union directive to regulate a new and disruptive technology is a major error. Up until very recently the technology was completely misunderstood in government and subject to a demonising campaign by the WHO and many health groups lobbying the European institutions with a prohibitionist agenda. This negativity has since been reversed in the UK, most notably by the publication of the authoritative Royal College of Physicians report on 28 April, *Nicotine without smoke*. The problem is that this has come two years after the directive was agreed based on flawed science and intensely negative interest group lobbying, and it may take a further 10 years before it can change. We enclose the RCP's highly positive recommendations and press release [3][4].

The EU directive is generating anti-EU pro-Brexit sentiment among Britain's 2.2m vapers. The Directive comes into effect on 20 May 2016 and is driving strong anti-EU feeling among some of Britain's 2.2 million vapers. Many are now vocally calling for "Brexit" and pointing to the Directive as evidence of how the EU harms its citizens and is an elitist and remote project indifferent or hostile to their concerns and aspirations. We have yet to find a single consumer who believes these EU measures will do anything beneficial for consumer protection, promote a vibrant rival to the cigarette trade or protect public health.

The making of the EU directive is a case study in bad policy-making. The relevant directive text was drawn up in the immediate aftermath of rejection by the European Parliament in October 2013 of the Commission, Council and UK's misguided policy to regulate these products as medicines. They are not medicines and never were. Completely new *ad hoc* regulation was concocted in a few closed 'trilogue' meetings, ignoring the advice of scientists, and with no consultation, options appraisal, impact assessment or Westminster scrutiny. The Department of Health had numerous opportunities to pull back from this but ploughed on undeterred. All the government's 'better regulation' machinery was supine and unresponsive. The 'Red Tape Challenge' was indifferent and disengaged, even though it notionally had an interest in new and disruptive technologies. If there is interest in learning from this woeful experience - the antithesis of 'open policy-making' - we would be happy to provide a more complete account.

What can be done?

We have suggested a number of actions to the Department of Health, and would like to reiterate them here:

- The Department of Health should thoroughly assess the impact of this directive as it comes into effect and report on adverse unintended consequences and impacts on smoking behaviour - the most likely consequences are large and harmful. We recommend annual review of the directive and its impacts.
- The Government should assess the supply chain and consumer reaction to the directive to determine whether the directive is really promoting the free movement of goods or merely promoting risky or criminal enterprise. The growth of any black market should be

treated as a diagnostic for policy failure rather than as a reason to treat people quitting smoking and protecting their health as criminals.

- The Department of Health should press for an early review of Article 20 by the European Commission. The directive requires a report no later than May 2021, but it could be done sooner.
- The Department of Health should press the Commission to recognise Article 20 is, at best, an interim stop-gap measure and to seek a new legislative proposal based on light-touch standards, realistic communication with consumers, and proportionate restrictions on marketing similar to those currently operating in the UK, which are in turn similar to those used for alcohol for many years.
- The Department of Health should seek legal advice on its options if the directive is not working as intended, and not promoting the free movement of goods with a high level of health protection. In this event we believe these provisions lose their Article 114 legal base under the EU treaties and become unlawful. In that event, they should be withdrawn regardless of whether legal action is taken.

These concerns are emphasised by the Royal College of Physicians at 10.4.2 in its April 2016 report [\[5\]](#)

...it is clearly important that TPD implementation be closely monitored to assess the extent of unintended, as well as intended, effects on the availability and use of non-tobacco nicotine products and, in particular, the consequences of these effects on tobacco smoking rates; it should also ensure that prompt action be taken if TPD regulation proves to work against, rather than for, the benefit of public health. We therefore recommend annual review in the UK.

We would welcome the opportunity to discuss these issues with the appropriate advisers or officials and would welcome your response to the five recommendations above. We are copying this letter to Nick Seddon (Special Adviser), to Anne Main MP, to Lord Prior and to Viscount Ridley, who initiated the debate in the House of Lords to which the question at PMQs refers.

Yours sincerely



Sarah Jakes (Trustee)
On behalf of New Nicotine Alliance



Clive Bates
Counterfactual
Associate, New Nicotine Alliance

Disclosures

The New Nicotine Alliance advocates for consumer interests in new nicotine technologies and is completely independent of commercial interests in the relevant industries (e-cigarettes, tobacco, pharmaceutical companies, etc).

Clive Bates is Director of Counterfactual, which is a sustainability consulting and advocacy practice. He is an Associate of the New Nicotine Alliance. He has no competing interests with respect to any relevant industries.

Enclosures

[1] Snowdon CJ, [E-cigarettes and Article 20 of the Tobacco Products Directive](#), EPICenter (European Policy Information Center), September 2015

[2] Letter from New Nicotine Alliance to Department of Health: [Assessing and mitigating unintended consequences of policies for vapour technologies and other low risk alternatives to smoking](#), [as sent - [PDF](#)] 29 April 2016

[3] Royal College of Physicians, *Nicotine without smoke*: [key recommendations](#), April 2016

[4] Royal College of Physicians, *Nicotine without smoke*: [news release](#) April 2016.

[5] Royal College of Physicians, *Nicotine without smoke*: [main report download](#) April 2016.