Red Tape Challenge for disruptive businesses – time to challenge e-cigarette regulation

The UK government has a process called the Red Tape Challenge, which has the aim of lifting unnecessary regulatory burdens on business. Within its broad remit it has a specific theme on disruptive or 'challenger' businesses. Its problem definition for this theme is as follows:

We understand that new business models – particularly those that involve doing things differently – may fall foul of regulations that were intended for another age, or for another purpose entirely. We want to ensure that our regulatory system is fit for purpose, and is not holding back disruptive new companies

I think that regulation of e-cigarettes as medicines fits this definition *very well*. If you are in the e-cigarette business as a manufacturer, importer or wholesaler and you are baffled or troubled by the MHRA's new licensing guidance, or you are retailer concerned about what this means to for your business, you can raise your concerns via this route. Take a good look at the guidance, and other MHRA documents, like its Q&A and paper on Proportionate Regulation, if you want to get up to speed.

I have submitted the contribution below via the Red Tape Challenge comment page (now working) and via the e-mail address (which you can use for private communication). *I don't advise a mass write in by users*, unless you have particular knowledge of regulatory impacts (write to the Minister for Public Health instead). My submission to the Red Tape Challenge is as follows (I have added proper hyperlinks, some highlighting and formatting etc for this posting).

From: Clive Bates
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The Regulation of E-cigarettes

1. I would like to raise the issue of the forthcoming regulation of 'e-cigarettes' – devices that heat a liquid carrying nicotine and flavourings to create a vapour that can be inhaled instead of smoking tobacco. This is a truly disruptive technology and is growing rapidly (50-100% per annum). It provides a source of nicotine for smokers that is probably two orders of magnitude (~99%) less risky than cigarettes. Some analysts believe that e-cigarette use will overtake cigarette smoking within a decade. Not only is it disruptive to the tobacco industry's cigarette-based business model, it could be one of the most significant public health developments of the century, which is my primary interest. It will succeed in this if the products are appealing, diverse and innovate and sufficiently attractive to cause smokers to switch.

2. The industry has been growing rapidly and thriving in its diversity and creativity with the normal consumer protection legislation applying. The government has now adopted the policy of treating these products as if they are medicines, and regulating them as medicines under the Medicines Act and EU directive 2001/83/EC. However this very closely fits the Red Tape Challenge problem definition in which innovative challenger technologies:

> *"may fall foul of regulations that were intended for another age, or for another purpose entirely".*

That is exactly the problem – these products are not medicines, they are consumer lifestyle products – a new and better way of using the legal widely used recreational drug nicotine (which in itself cause little harm – analogous to caffeine). The users do not regard themselves as in therapy and the vendors are not selling a treatment. The definition of these products as medicines fails both as common sense and legally (four cases in Europe have overturned the definition and it was rejected in the US courts when the FDA tried the same classification).

3. Medicines regulation would be merely inappropriate and ill-judged if it was 'light touch' and did not threaten the dozens of small and medium enterprises

that make up the UK industry. However, the proposals for regulating e-cigarettes are extremely burdensome, costly, restrictive and disruptive – probably ruling out all the products currently on sale in in this thriving market and requiring each company to scrap its existing supply chain (which are mostly not pharmaceutical grade facilities and many based in China). Furthermore, in pure public health terms there is a balance to be struck between the exacting standards set for licensed products and the appeal of the category as whole to smokers. The dominant health objective is served by having as many smokers as possible switch to e-cigarettes. A few bland but highly regulated commoditised products may not be the best way to appeal to smokers. Excessive regulation would not only raise costs, but it would reduce the range of products on the market (it would be uneconomic to seek marketing authorisation for products with small sales), raises regulatory risks with a cooling effect on innovation, slow the product refresh cycle, and create barriers to innovation and creativity. Medicines regulation would come with other limitations arising from the (understandable) conservatism of medicines regulators – for example there is no need for medicines to come in 200 flavours, but this is part of the intrinsic appeal of e-cigarettes.

New MHRA Guidance on Application for a Marketing Authorisation

4.I am writing now, because last week the regulator, the MHRA, released guidance on the requirements for manufacturers, importers and wholesalers on requirements for submitting an application for a marketing authorisation. This shows just how burdensome this process would be: Licensing Procedure forElectronic Cigarettes and Other Nicotine Containing Products (NCPs) as Medicines.

The Government's Approach

5.The Coalition has maintained the approach of the previous government and has supported the application of medicines regulation both domestically for its own tobacco control policy. It also supports this approach at EU level in the context of the revised Tobacco Products Directive Directive now working its way through the European Parliament and Council through the Ordinary Legislative Procedure. However, I believe the support for this has been largely

based on a false premise: that medicines regulation would be 'light touch'. It simply is not light touch and cannot be.

Scepticism from Regulatory Policy Committee

6.This approach drew well-founded scepticism from the Regulatory Policy Committee (see Opinion: consultation on regulation of nicotine containing products) – and its points remain unaddressed in any public form.

Poor Impact Assessment

7. The major concerns about impact on the supply chain were sidestepped in the Impact Assessment used to support the UK's Council position in the EU negotiations over the directive. It is worth quoting paragraphs 53-56 of this document to highlight just how careless this IA is about impact on existing business (note: a few highlight in red – emphasis added):

> *53. Note that we have not included the costs of achieving Good Manufacturing Practice (GMP). Currently all manufacturing is conducted outside the EU and we have assumed that in the first instance, the foreign manufacturers would bear the costs of achieving GMP.*
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> *54. We have also assumed that any production that might be established within the EU in the future would bear similar costs of achieving relevant manufacturing standards regardless of whether the UNCPs come into the scope of medicines regulations or not.*
>
> *55. It is likely that foreign manufacturers, EU MA holders, and all other participants in the supply chain would seek to pass their incremental costs onto their buyers, and ultimately to consumers. The extent to which UK consumers would bear the incremental costs is a moot point. Pricing of NCPs seems to be constrained at the upper bound by the pricing of tobacco products, and hence to a considerable extent, we would not expect NCP consumers to suffer from substantial price increases after policy implementation. Nevertheless, bringing currently unlicensed NCPs into scope of medicines regulation is likely to introduce considerable barriers to market entry, which could limit competition and hence deprive consumers of price reductions that would otherwise occur under the "do nothing"*

option.

56. Although in the long term we would not expect owners of the capital invested in the manufacture and supply of NCPs to suffer losses, there would likely be short term transitional losses for some stakeholders, not least current importers of UNCPs who would be unwilling to invest in gaining the necessary authorisations and licenses. However, it seems likely that these stakeholders would be able to redeploy their capital and expertise quickly to other activities, and hence their losses would be limited."

8. In fact, even this is an optimistic assessment. It cannot be assumed that third-country manufacturing facilities can or will meet the GMP standard to the level required by UK/EU inspectors. Nor has anything been done to show this is necessary or value for money (the costs have not even been estimated). It is possible that UK firms buying overseas do not have any intellectual property (ie. design of devices) and therefore cannot take their manufacturing elsewhere. The impacts of this form of regulation are not simply those stated (higher prices) they are supply chain disruption, reduced product diversity, barriers to innovation and SME closures (or 'consolidation' as it can be euphemistically stated).

Consultation

9. It should be noted that consultation with affected stakeholders on this approach has been minimal. A 2010 MHRA consultation, which was deeply flawed and heavily criticised, simply asked if e-cigarettes should be regulated as medicines, without detailing the implications – and with the stated MHRA preferred option at the time to take all the products off the market within 21 days of classifying the products as medicines (thankfully users objected in large numbers). At EU level the Commission's consultation has done no more than ask if e-cigarettes should included in the revised Tobacco Products Directive. The manufacturers, importers and wholesalers of nicotine containing products have had no opportunity to understand or respond to the requirements of medicines regulation. The new document is not produced for consultation, but as guidance on a settled process.

Legal Issues

9. Regulation at European Union level must meet tests for adequate legal base, proportionality, non-discrimination, minimum burdens and adequate consultation. When compared to the regulation of cigarettes or even novel tobacco products, this approach fails several legal tests and is vulnerable to legal challenge. The industry trade association ECITA has taken advice from Sir Francis Jacobs QC available here. Further, these products must fit within the legal definition of a medicine in the medicines directive, which they do not (see: Are E-cigarettes medicines?)

The Right Approach

10. There are two approaches. In the short term, rely on the extensive body of safety and consumer protection legislation that already exists, introducing new standards as necessary. Rigorous application and enforcement of at least 17 applicable directives would be a proportionate response (especially give most nicotine is consumed via a filthy aerosol of burning tar particles and hot toxic gases). See list of directives here.

11. In the longer term, insist on purpose-built regulation that is fit for purpose. A much better model for this is the approach taken to cosmetics – diverse lifestyle FMCG products that can pose risks to the human body. Cosmetics makers have the right to place products on the market if they comply with the regulation (medicines cannot be placed on the market unless authorised). Lessons from cosmetics regulation are drawn here.

Request for Red Tape Challenge

12. My request is for the scrutiny processes of the Red Tape Challenge to be applied urgently and thoroughly to the regulation of this rapidly growing challenger sector, and for there to be a proper consultative approach in which the industry can engage via this process. This needs to happen very rapidly: the EU Tobacco Products Directive will likely be settled later this year; after a serious procedural breach, the public health minister will face further scrutiny of the government's position by the European Scrutiny Committee of the House of Commons; and the proposals of the MHRA and government are causing uncertainty in the industry – and it is important that a sound regulatory

strategy is adopted as soon as possible. If the UK government changed its approach at EU level, I believe it would find support from other member states – France has already entered its reservations.

Disclosure

13. Though I am not an industry player, I am aware of widespread concern in the e-cigarette industry at all levels, and among users, about these developments. I am former Director of Action on Smoking and Health (1997-2003) and a former public servant (2003-2012). I now run my own consulting and advocacy practice – Counterfactual Consulting. I have no competing interests. These views are my own and not necessarily those of former employers.