

# **Costs and burdens of medicines regulation for e-cigarettes**

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# 1 Overview: the e-cigarette market – a solution not a problem

E-cigarettes are very low risk alternatives to cigarettes, used by smokers as a pleasurable way of taking the relatively harmless recreational drug nicotine.

The market in the UK is growing rapidly: there are around 1.3 million users and growth rates exceeding 50% per annum. The uptake of electronic cigarettes has been a relatively quiet consumer led revolution. There has been no public health input or encouragement, and no spending of health service resources. The growth in popularity has come about mainly by word of mouth and internet advertising.

There are hundreds of products on the market in thousands of variations allowing for strong personalisation. Many users, often committed heavy smokers, report switching to e-cigarettes as a transformational experience. Many are cutting down their smoking and are on a journey towards complete smoking cessation. There is a vibrant industry of perhaps 300 successful and emerging small and medium enterprises (SMEs) all over the UK either making and marketing products, or importing and reselling from manufacturers in the Far East. Larger players, including tobacco industry subsidiaries, are becoming involved and will bring technology, marketing and distribution reach. In the consumer base, there is a vibrant social media scene, on-line peer support and advice, and many passionate individuals prepared to give their time and advice to new users. There are poor products on the market, but they are being superseded by superior products through the normal processes of consumer choice and supplier innovation interacting in a competitive market.

There are already 17 European directives and regulations that manage general safety, electrical safety, packaging and labelling, quality and fair commercial practices in this market<sup>1</sup> (see Annex). They are not 'unregulated', as some have claimed, and a voluntary industry code has raised standards and assisted trading standards officers in targeting poor quality producers<sup>2</sup>.

The main threat to this active and highly beneficial market is excessive and poorly conceived legislation, notably the policy of regulating these products as medicines. The MHRA<sup>3</sup> and the UK government have announced their support for European Commission proposals<sup>4</sup>, which would ban nicotine containing products above a certain (low) threshold if they are not licensed as medicines.

*However, there are no problems that justify a further dramatic regulatory intervention, and the rationale for intervening in this way is weak and unconvincing.*

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<sup>1</sup> See Bates C. *E-cigarettes are unregulated right? Wrong*. Counterfactual <http://www.clivebates.com/?p=1092>

<sup>2</sup> ECITA, The Industry Standard of Excellence. <http://www.ecita.org.uk/theise.html> – accessed 14 September 2013.

<sup>3</sup> MHRA, Nicotine Containing Products <http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice%E2%80%93M%E2%80%93T/Nicotinecontainingproducts/index.htm>

<sup>4</sup> <http://ec.europa.eu/health/tobacco/products/revision/>; the process is described in <http://www.clivebates.com/?p=1472>

Medicines regulation for e-cigarettes will:

**Create a de facto ban on most products.** Medicines regulators can't explain how they will deal with thousands of combinations of flavour, strength, excipient and nicotine density. Because each would need a licence the vendors would need to bear costs running to billions of pounds, or more likely drastically reduce the range of products - yet it is diversity and personalisation that are key to the appeal to smokers. Despite what regulators claim, this is a ban in practice on many products and will be seen as such by users.

**Destroy the existing supply chain and most businesses.** The products will need to be manufactured in pharmaceutical industry production and distribution facilities. The investment cost or difficulty of securing compliant outsourcing contracts will wipe out the existing supply chain and almost all vendors in the market today, replacing them with either tobacco company affiliates cross-subsidised from their tobacco business, or pharmaceutical companies - which look reluctant and don't like or understand the market.

**Make e-cigarettes harder to buy than tobacco cigarettes.** In many countries in Europe medicinal products would only be available in pharmacies or other approved premises. People need access to these products at the times and places they can buy tobacco cigarettes. It makes no sense to restrict availability of e-cigarettes to below that for cigarettes - and even if member states could in theory change this, they won't.

**Favour the cigarette industry.** There are many aspects of medicines regulation that impose expenses, burdens or restrictions that are high, unnecessary and not imposed on the cigarette industry (or others such as the drinks industry). For example pharmacokinetic tests, pharmacovigilance, certain qualified personnel, exacting quality control standards, pre-approval of packaging and advertising.

**Induce significant legal risk.** It is quite clear that e-cigarettes are not medicines and that banning them because they do not comply with medicines regulation creates significant legal risks. There will almost certainly be legal challenges by those excluded from the market by medicines regulation, and Counsel's opinion suggests they have a high chance of success in having the measure annulled as disproportionate.

**Create unintended consequences high and unnecessary barriers to entry for firms and products.** The effect will be forced closures of existing firms and consolidation into a few tobacco industry backed affiliates selling compliant commodity products at higher prices and with little choice for users, with a sluggish pace of innovation and improvement. Users will not be passive: excessive regulation will promote more home mixing, internet trade, and black market activity. That will create an unregulated space with greater health risks and more criminality. It will also mean many will return to smoking or never make the sustained switch that gives us the big public health result.

In short, medicines regulation focuses on creating a better medicinal product, whereas the public health is served by having better alternatives to cigarettes.

#### **Recommendations:**

The government should revisit the policy of treating e-cigarettes as medicines.

The government should:

- Immediately reserve its position on e-cigarettes (Article 18) in the context of the Council deliberations on the Tobacco Products Directive. The French government did exactly this at the Health Council meeting of 21 June 2013. The UK government should do the same until it has properly assessed the impacts and ministers are clearly sighted on the consequences for the businesses and users involved and the potential damage to public health.
- Initiate a 'Red Tape Challenge' process on the application of medicines regulation to e-cigarettes under the 'challenger business' theme of the Red Tape Challenge. This should consider alternative approaches, for example standard setting.
- Prepare an updated Impact Assessment that addresses the deficiencies raised in this report and properly assesses the impacts on the existing e-cigarette industry.
- Invite the Regulatory Policy Committee to examine the current proposals, the impact assessment and process followed and to provide advice to ministers.

The Department of Health, with support from the Department for Business, Innovation and Skills should:

- Urgently examine non-medicines options for proportionate regulation that meets the government's better regulation and red tape objectives. The MHRA is bound to medicines regulation and cannot therefore do this.

The E-cigarette industry should:

- Commit to strengthening and formalising its own code, the Industry Standard of Excellence, and to do more to assist trading standards officers in applying risk-based regulation.

## 2 Major issues in applying medicines regulation to e-cigarettes

We believe many in government and European institutions have agreed to support medicines regulation on the basis that it would be 'light touch' – that it would involve a rapid and inexpensive process that would raise product quality and safety standards. If this were the case, most of the current industry would be supportive. However, the medicines regulation regime is far from 'light touch' and will eliminate most of the existing supply chain, raise significant barriers to entry and create costs and burdens that will be unbearable for most or all of the existing industry. The impact assessments provided so far by the MHRA<sup>5</sup> and European Commission<sup>6</sup> are an inadequate assessment of the impacts of applying medicinal regulation to e-cigarettes. Major impacts on manufacturers, distributors and retailers currently in the market have been ignored or no quantification has been made of several serious impacts. We do not believe these issues have been adequately exposed to decision-makers. The main weaknesses are discussed in the remainder of this section.

### 2.1 Disproportionate costs of achieving Good Manufacturing Practice

Medicines regulation requires that manufacturers and distributors comply with Good Manufacturing Practice (GMP). GMP is not a vague statement of good intent, it is a precise high specification standard for pharmaceutical production<sup>7</sup>. It requires significant investment in design, manufacturing facilities, automation, process controls, information technology and human expertise. It would require mostly China-based facilities to face licensing and inspection by EU-approved inspectors who will determine if they meet the GMP production and quality standards for pharmaceuticals sold in the EU.

**Purpose of GMP for medicines.** GMP makes sense for genuine medicines because risks arise from over-dosing, under-dosing and side-effects, and therefore process controls are required to ensure medicines are produced to exacting standards of purity or consistency – within and between batches and through the shelf life of the product. This precision is unnecessary for e-cigarettes, as users control the dose they take by how they draw on vapour – varying depth and frequency of puffs to achieve a satisfactory experience. Whilst absolutely consistent performance might be *desirable* in an e-cigarette, it is not *necessary*, and without elaborate control electronics built into the product design, it is not achievable. E-cigarettes are battery-powered devices and the batteries lose power between charging and over their life. Users are aware of that and compensate – it is not important in the same way that it would matter a device used for medicinal purposes.

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<sup>5</sup> MHRA, Impact Assessment – Unlicensed Nicotine Containing Products, June 2013. Impact assessment to support the UK's position in EU negotiations on the regulation of Nicotine Containing Products, which are currently being considered along with changes to the Tobacco Products Directive <http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con286852.pdf>

<sup>6</sup> European Commission, Commission Staff Working document SWD(2012) 452 final December 2012 [http://ec.europa.eu/health/tobacco/docs/com\\_2012\\_788\\_ia\\_en.pdf](http://ec.europa.eu/health/tobacco/docs/com_2012_788_ia_en.pdf)

<sup>7</sup> MHRA, Good Manufacturing Practice, <http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodManufacturingPractice/index.htm>

**Impact assessments avoid GMP impacts.** It is difficult to estimate the costs of attaining GMP and it will be specific to each company's business model. For manufacturing, it is likely to require investments measured in tens of millions of pounds. However, the costs and impacts of being held to the GMP standard are not even included in the MHRA's Impact Assessment (IA). The following text is included:

*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.*

This statement conceals very significant problems for the existing industry. The assumption that foreign manufacturers will bear the costs is based on a misunderstanding of how contract medical device manufacturing works. The e-cigarette business needing to meet a new manufacturing standard would bear the costs of machinery and general plant upgrade – they pay for the necessary investments and bear volume risk through upfront investment and guaranteeing a minimum purchase, subject to penalties. It is unlikely that the predominantly Chinese suppliers will be either able or willing to make these investments spontaneously and prospectively. The effect will be to destroy the supply chain upon which most UK firms and consumers rely. The MHRA's IA does recognise that disruption will arise:

*55. [...] 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.*

It is these 'barriers to entry' that should concern ministers. In the industry's view, the barriers will be exceedingly high, as they will require complete rebuilding of the supply chain for most products and most firms in the market today. For many companies that simply is not possible. It is not only a matter of costs increasing, but these barriers to entry will forcefully eliminate most existing firms. The IA continues, recognising but failing to quantify this impact:

*56. [...] there would likely be short term transitional losses for some stakeholders, not least current importers of UNCPs [Unlicensed Nicotine Containing Products] 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.”*

This language is describing government indifference to small companies going bust because they cannot meet the requirements of medicines regulation. The impact of “short-term transitional losses” is not estimated in terms of duration or depth, and for its impact on the industry. In our view, these costs are significant and require the financial strength to bear significant losses – a position that only favours affiliates of major corporations with strong balance sheets.

## **2.2 Excessive costs and burdens of the medicines quality management regime**

The GMP regime is one part of a larger quality control system that is employed in the pharmaceutical industry and required by regulators. Other standards, the so-called GxP standards, apply to laboratory practice (GLP), clinical practice (GCP), distribution (GDP) and pharmacovigilance

(GPvP). These standards extend through every part of the business, through the wholesale supply chain. The standards are exacting and subject to assessment by relevant inspectorates<sup>8</sup>. An e-cigarette company might need 200-300 Standard Operating Procedures to meet these standards and an IT infrastructure to support control and change management of this framework. The in-house personnel and specialist consultant costs are substantial: a company needs to employ a Chief Medical Officer and various 'Qualified Persons' to undertake particular functions such as product release and quality management. As the products being sold are medicines, it is also a requirement that sales and marketing staff are qualified and abide by the Association of the British Pharmaceutical Industry Code of Practice, and the Proprietary Association of Great Britain Advertising Code as appropriate<sup>9</sup>. For companies in the pharmaceutical industry, these processes are already part of their business model and any extension to an e-cigarette or Nicotine Replacement Therapy (NRT) category is marginal. But to others these standards are very burdensome, unfamiliar, and plainly not possible for those companies with a wide range of products. The requirements pose a significant barrier to entry – and they are also disproportionate and unnecessary.

### 2.3 Severe impact of licensing restrictions on the range of products available

Medicines are sold for their therapeutic qualities, e-cigarettes for their appeal as consumer products. This is a fundamental difference: medicines never come in a range 150 flavours, for example. But for e-cigarettes to be successful, they have to appeal to smokers – not only as a satisfactory replacement for smoking-derived nicotine and the ritual aspects of smoking, but also as a pleasurable activity. The public health benefit is driven by the *appeal* of these products to people who would otherwise smoke. The very large variety of e-liquid flavours, mixtures atomisers and batteries is central to the appeal and success of these products, allowing customisation and a personalised experience.

**Almost all flavours would be banned.** Most flavours on sale are approved for use in foods, but different rules apply to pharmaceutical ingredients, and inhalation is different to eating. In the absence of clear guidance to the contrary from the MHRA, we understand that only those flavouring agents listed as approved for inhalation in the *European Pharmacopoeia* would be permitted in e-cigarette products licensed as medicines. We understand this has two flavours approved for inhalation use (eg. for asthma inhalers), but would welcome official clarification that that is the case. Whilst applications can be made for addition of new flavours to the *European Pharmacopoeia*, we expect this to be an expensive, slow and burdensome process. It is likely that few individual firms in the market would be able or willing to make such an application and no more than a few extra flavours are likely to be added - certainly not for the hundreds of flavoured products currently on the market. We do not know how the various tobacco flavours would be treated, but even within this category there are dozens of variations. This restriction on flavours would force a dramatic restructuring of the industry – favouring a few homogenised, high volume products.

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<sup>8</sup> For more information, see MHRA Inspection and standards web pages <http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/index.htm>

<sup>9</sup> See Association of British Pharmaceutical Industries (ABPI) Code of Practice and exams <http://www.pmcpa.org.uk/thecode/Pages/default.aspx> and Proprietary Association of Great Britain Advertising Code <http://www.pagb.co.uk/codes/advertising.html> . Different elements of these codes apply for sales to health and medical sales and GSL sales.



In its impact assessment<sup>10</sup>, the European Commission included a ban on flavourings in one of the options in its options appraisal (see option PO1 on page 77) and regards it as likely that flavours would be banned under medicines regulation:

*In particular NCP with characterising flavours are unlikely to be authorised under the medicinal products' legislation (page 81)*

A removal of the vast majority of flavours from the market would not simply be raising standards, but radically reshaping the product and diminishing its appeal. Such restrictions are wholly disproportionate: it is important to remember that these products compete with cigarette use, which causes inhalation of thousands of chemicals, many toxic or carcinogenic.

## 2.4 Severe impact of licensing costs on the range of products available

Even if restrictions were somehow waived or loosened, a further problem would arise. This is closely related to the importance of 'personalisation' in this market – the idea that users explore combinations of flavour, nicotine strength, excipient mix (ratio of Propylene Glycol and Vegetable Glycerine) and adjustments for 'throat hit' that work for them. A company might have a range with:

- 150 flavours
- 2 flavour strengths
- 6 nicotine strengths
- 3 excipient mixes
- 2 throat hit varieties

That range amounts to 10,800 theoretical product variations. MHRA has confirmed that each strength needs a separate Marketing Authorisation (MA) but has not clarified how it will consider other combinations. However, as all the other variations represent different product formulations we would expect them to require separate MAs unless informed otherwise – and guidance produced so far has not addressed this. The July 2013 MHRA guidance to e-cigarette companies<sup>11</sup> does not even contain the word 'flavour'.

The MHRA impact assessment<sup>12</sup> (para 51) gives estimated costs for licensing a *single* product. These costs are given as a range:

Total costs	One off	Annual recurring	Present value	Cost annualised over 10 years
<b>Lower estimate</b>	£252,000	£65,000	£747,000	£87,000
<b>Upper estimate</b>	£390,000	£249,000	£2,288,000	£266,000

A simple multiplication of the single cost and number of product variations in this hypothetical case

<sup>10</sup> European Commission, Commission Staff Working document SWD(2012) 452 final December 2012 [http://ec.europa.eu/health/tobacco/docs/com\\_2012\\_788\\_ia\\_en.pdf](http://ec.europa.eu/health/tobacco/docs/com_2012_788_ia_en.pdf)

<sup>11</sup> MHRA, Licensing procedure for electronic cigarettes and other nicotine containing products (NCPs) as medicines, July 2013 <http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con297583.pdf>

<sup>12</sup> MHRA, Impact Assessment – Unlicensed Nicotine Containing Products, June 2013. <http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con286852.pdf>

gives absurdly high numbers (£8-25 *billion* present value). Obviously that cost would and could not arise in practice. However, the problem is not with the illustrative calculation but with the failure of the impact assessment to estimate the real-world costs for a company with a typical product range<sup>13</sup>.

The likely effects of having to make individual applications or even MA variations is that firms will have to dramatically reduce the permutations available – reducing the extent of personalisation and diminishing category appeal. We should expect licensing costs for product variations to be significantly lower than a one-off ‘first of a kind’ application. But no figures are given for ‘Nth of a kind’ (NOAK) applications, and no effort has been made to assess the impacts on a business with more than a single product. The assessment is more suited to the business model of a large tobacco or pharmaceutical manufacturer selling a single high volume integrated device and liquid cartridge. However, that is only one of many business models in the market place. The true impact on a typical business, though somewhat less than £8-25 billion, could still be exceedingly high or alternatively, cause it to radically contract its product line.

**Impact on the market leader.** Even for a simple but relatively large company in this market these licensing costs are substantial. The leading UK company Zandera (with the E-lites brand) has a current (2012-13) turnover of £18m. Zandera believes it has four products that would require licensing. Taking mid-points in the table above (which makes no allowance for NOAK savings), this would mean costs of £1,284,000 one-off, £628,000 annual, and present value of £6,070,000. These figures are substantial fractions of the current company turnover, yet this is the market leader at present. As discussed above this does not include the much larger costs associated with attaining GMP standards.

## **2.5 Burdensome application process and information requirements**

The application process costs are significant and require expert involvement that most UK e-cigarette vendors do not have access to. In its guidance, MHRA lists a range of information requirements and literature searches needed to support a Marketing Authorisation Application (MAA).

It is understood within the industry that one MAA now in progress runs to 10,000 pages including all supporting documentation, though we do not have official confirmation of that from the MHRA or the applicant. We suggest that ministers ask to see the documentation for an e-cigarette MMA in full. A 10,000 page application is not ‘light touch’ by most definitions.

## **2.6 Unclear purpose of tests required for a license application**

The licensing regime requires a number of tests to be undertaken for each product going through a MMA. By allowing applications under Article 10.1 or 10.3 of the Directive<sup>14</sup>, it is clear that MHRA intends to relieve applicants of the burden of clinical trials, and it is likely that this is the ‘light touch’ part of the process. Nicotine is widely used by millions of smokers and thousands of NRT users, and

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<sup>13</sup> This is not an unrealistic example. One real world company has 152 flavours with 3 strength of flavour variations, 4 pg/vg variations, 8 nicotine variations and 3 throat hit variations. This creates 43,776 possible variations in formulation.

<sup>14</sup> The legal basis for all types of application is set out in [Directive 2001/83/EC](#) and in [Regulation \(EC\) No726/2004](#).

it is thought to have risks analogous to caffeine.

However, there is still a requirement to conduct pharmacokinetic and pharmacodynamic tests to support a safety and 'efficacy' case. Absent any medicinal, therapeutic or smoking cessation aid claims we do not see the legitimacy of these tests *as a requirement of regulation*, though it is likely that more manufacturers will want to use such tests to develop understanding of these characteristics to help build better products. From medicinal safety perspective, users control the dose they receive, and they are not at physical risk if the dose is different to their expectation. 'Efficacy' can only relate to a desired 'effect'. With an ordinary medicine, the relevant effect is that made in a therapeutic claim. Given that no therapeutic claims are made by e-cigarettes producers, it is not clear what function these tests perform. If it is to ensure they are good recreational products that consumers find satisfying, then that is not for a medicines regulator to determine. As long as no misleading claims are made, it is up to consumers to decide what constitutes a product they choose to buy.

## **2.7 Discriminatory and unnecessary risk management and surveillance obligations**

On 12 June 2013, the MHRA published a paper on what it calls 'right touch regulation'<sup>15</sup>. In this it described elements of the regulatory regime including a section on risk management.

*2.3.2 Currently available information indicates that what might be considered the major issues (use by current smokers long term particularly with partial substitution: ex-smokers: non-smokers: children/ adolescents) with GSL [General Sales List] availability of a licensed ENDS/e-cigarette or other device delivering nicotine via the pulmonary route do not raise any undue concerns. Nevertheless the risk management plan (RMP), mandatory if such an application were granted, will need to address these potential concerns with "real life" usage data, so the key part of the RMP should outline how the MAH [Marketing Authorisation Holder] propose to investigate:*

- *The potential 'attractiveness' of the product to under 18s. Is there any appreciable use both when the product is first marketed and does this change over time?*
- *Whether non-smokers and ex-smokers are using the product? Also looking at changes over time.*
- *Pattern of use of the product including*
  - *reason for use*
  - *how long used for*
  - *concurrent tobacco use*
  - *have quit attempts been made?*

*In addition, particular characteristics of the device, its presentation and other relevant factors may dictate further areas for investigation.*

Apart from the problems that it is extremely difficult to assess these issues when there is a myriad of different products and combinations in use, we simply point out that none of this is required of the

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<sup>15</sup> MHRA, Working group on nicotine containing products. Right Touch Regulation. 2013  
<http://www.mhra.gov.uk/home/groups/comms-ic/documents/websitesources/con286850.pdf>

primary competitors to e-cigarettes companies, the far more dangerous cigarette industry. These questions are no less interesting in the case of fast food or alcohol, but the drinks industry or MacDonald's are not required to track the use of their products in this way. Furthermore, it is an unconventional use of risk management in medicines regulation. The legitimate reason for surveillance and risk management of medicines is to track the emergence of adverse reactions or other problems that only become visible when many people use the product over a prolonged period. Regulators should only require information that is necessary for making regulatory decisions<sup>16</sup>, not to provide population data on consumers or the marketplace more generally.

The industry accepts that an overall surveillance regime is of value in policymaking. However, this should not be done as a condition of a Marketing Authorisation – this is as an extremely cumbersome way to approach it that will be beyond the reach of most vendors. The broad picture of e-cigarette use could and should be effectively captured through the Smoking Toolkit Study<sup>17</sup> or an equivalent designed for the purpose. This simple and highly valuable option does not appear to have been considered as it falls outside the purview of medicines regulation, which requires a mandatory risk management system for each marketing authorisation. Even if it was possible to provide such information, it is far from clear how the MHRA would interpret this information and what they would do with it. For example, signs of increasing use of e-cigarettes by young people might be a cause for concern, but much less so if this was an alternative to smoking. How would a regulator adjust a marketing authorisation in response to this observation?

## **2.8 Unwarranted forced restructuring of the market and industry**

Under the pressures of regulation discussed above, the high barriers to entry associated with GMP and the high specific costs of each MAA will force a traumatic restructuring in the market place. The market will become dominated by the few firms, mostly affiliates of tobacco companies, with the scale and balance sheet support to make the required investments. The range of products available will contract dramatically, leaving a few commodity products with volume that could bear the costs of the licensing. One vendor which already applies quality control through laboratory testing of its liquids and compliance with relevant electrical and hazardous substances regulations, summarises the impact of moving to medicines regulation<sup>18</sup>:

*"...Marketing authorisation will not be possible for us, it would mean we'd have to change our business model into one that offers a restricted variety of products that would no longer work for our customers, and from our own research, our customers would either return to smoking, or import their own supplies direct from China, where they would not necessarily be subject to rigorous testing for either the safety of the liquid, or the safety of the electrical parts..."*

## **2.9 Dampening effect on innovation and creativity**

The introduction of a significant hurdle to bring a new product to market or for new firms to enter

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<sup>16</sup> One of the eight Hampton principles of better regulation (2005) is: *Businesses should not have to give unnecessary information, nor give the same piece of information twice.*

<sup>17</sup> Smoking in England, Smoking Toolkit Study <http://www.smokinginengland.info/sts-documents/> . Smoking In England is the portal through which major findings from the Smoking Toolkit Study and other national data are made available to policy makers, clinicians, researchers, journalists and the general public.

<sup>18</sup> Dr David Upton, personal communication. 15 September 2013.

will slow rather than encourage innovation and improvements in products that actually appeal to users. It will lengthen the product update cycle as it will not be worth bearing the costs of seeking an MAA for incremental improvements. It will force the *type* of innovation into that deemed important for medicines – for example consistency of ‘dose’ (even though users control the dose).

It is revealing that in the fixed and variable costs are annualised over ten years. This may reflect pharmaceutical innovation model where prolonged effort goes into drug discovery and then revenues flow from a patent-protected stable monopoly over many years. In the case of generics there is no product innovation. The innovation model in fast-moving consumer goods is quite different – it involves finding what works for consumers in trials or in the market place, with firms competing to attract demand with better products – with innovation happening over months rather than years. Medicines regulation will not create better e-cigarettes, it might create better medicines.

## **2.10 Negative implications for specialist high street retailers**

The small specialist high street retailers and some internet retailers provide a source of personalised advice and specialist knowledge on vaping. The retail sector would not need to hold marketing authorisations. However, if medicines regulation means there a just few commoditised products on the market and a few larger firms supplying them, then the specialist retailers will lose their basic business rationale and most will close. They would be indirect victims of regulation and the change this would cause in market structure.

## **2.11 Increased legal, regulatory and political risk**

Most new industries benefit from appropriate and stable regulation. The prospect of regulatory change creates uncertainty and makes external financing more difficult and expensive. The forced designation of e-cigarettes as medicines will increase regulatory and political risk, rather than provide a stable framework. The reason is that this designation is very vulnerable to legal challenge. It is likely that challenge will come from those harmed by the regulatory burdens arising from medicines regulation. A challenge would draw on the principles of free movement of goods, proportionality and non-discrimination, and various process failings, including inadequate consultation.

It is not only the industry that does not see e-cigarettes as medicines when no therapeutic claim is made. The MHRA now considers that a medicines marketing authorisation is not a requirement for an e-cigarette if no therapeutic claim is made. For example in its Q&A<sup>19</sup> it states:

***25. Why is the MHRA leaving unlicensed medicines on the market if there are no guarantees on safety, quality and efficacy?***

*Existing electronic cigarettes on the market, and other NCPs that make no medicinal claim, will not require a medicine licence until the European Commission’s revised Tobacco Products Directive is transposed into UK law*

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<sup>19</sup> MHRA, Questions and answers on the regulation of nicotine containing products, June 2013  
<http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con286835.pdf>

However, the legal framework for medicines is already in place and would not be changed by the Tobacco Products Directive. The effect of the TPD is to ban NCPs/e-cigarettes not licensed as medicines. In doing so, it requires a product that is not a medicine (otherwise the statement above would not apply) to seek approval as a medicine. It is easy for the layman to see the legal vulnerability in this, but it has been assessed in detail by Sir Francis Jacobs QC, a former Advocate General of the European Court of Justice, who concludes<sup>20</sup>:

*In our view this is an unreasonable measure, which is liable to be annulled as being contrary to the principle of proportionality and/or the principle of non-discrimination.*

Elsewhere, the mis-categorisation of e-cigarettes as medicines has been successfully challenged in five cases in member state courts<sup>21</sup>. Outside Europe, the US FDA's attempt to classify e-cigarettes as drugs was successfully challenged in the United States Court of Appeals in 2010.

By attempting to regulate e-cigarettes as medicines, when it is clear they are not medicines, governments are unnecessarily adding regulatory and political risk. That will make it difficult to secure investment and will ultimately penalise companies that do make investments or put effort into applying for marketing authorisations that turn out to be unnecessary.

## **2.12 Excessive and counter-productive restrictions on marketing**

Packaging, branding, product names, insert leaflets and advertising will require prior-approval. For example, MHRA states<sup>22</sup>:

*The Agency has also met with all existing NRT MAHs to make clear a willingness to consider innovative proposal for packaging – within legal constraints. [...]*

*The MHRA would propose to use its powers to pre-approve the advertising of any newly licensed product to ensure the requirements of medicines advertising were met.*

The MHRA has agreed to use the Proprietary Association of Great Britain<sup>23</sup>, which is a pharmaceutical industry body, to manage the legal requirements pertaining to medicines marketing, and all e-cigarette companies would need to join this body to have their marketing approved. It is difficult to know how much this will drain the creativity from e-cigarette marketing, but it should not be assumed this will necessarily serve the interest of better health. The greatest health benefit will be secured by having strong e-cigarette brands that can rise to compete with the declining equity of tobacco companies' leading brands as the effects of restrictions on tobacco advertising and packaging are felt over many years. There is a danger of excessive risk aversion or oversensitivity on

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<sup>20</sup> Sir Francis Jacobs QC, Opinion: in the matter of the revised tobacco products directive. July 2013. For ECITA <http://www.ecita.org.uk/blog/index.php/the-full-text-of-sir-francis-jacobs-qcs-opinion-on-the-legality-of-medicines-regulation-of-electronic-cigarettes-in-the-revisions-to-the-tpd-and-elsewhere/>

<sup>21</sup> European cases summarised in Bates C. *Are e-cigarettes medicines?* Counterfactual Ltd. March 2013. <http://www.clivebates.com/documents/areecigsmedicines.pdf>

<sup>22</sup> MHRA, Working group on nicotine containing products. Right touch regulation. 2013 <http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con286850.pdf>

<sup>23</sup> PAGB, Advertising Codes <http://www.pagb.co.uk/codes/advertising.html> and Pack Design Codes <http://www.pagb.co.uk/codes/pack.html>

the part of a regulator, perhaps responding to pressure from campaigners, that will prevent effective 'edgy' marketing. This could leave the products appearing sanitised, medicalised and bland, as with NRT marketing now. These restrictions will create a further negative impact on the appeal of the product to smokers.

**Comparison with alcohol.** Given the harm-reduction potential of e-cigarettes, we can see no reason why e-cigarettes should be more restricted in marketing terms than, for example, alcohol. Alcohol advertising is not subject to prior-approval by a regulator, but complies with a code of practice described as follows by the Advertising Standards Authority<sup>24</sup>:

*The stringent rules, which apply across all media and are mandatory, place a particular emphasis on protecting young people; alcohol ads must not be directed at people under 18 or contain anything that is likely to appeal to them by reflecting youth culture or by linking alcohol with irresponsible behaviour, social success or sexual attractiveness. The TV and radio advertising rules contain strict controls about the placement and content of alcohol advertising. Alcohol ads are banned from appearing in and around programmes commissioned for or principally targeted at audiences below the age of 18, as well as programmes likely to appeal particularly to audiences below the age of 18.*

An appropriately designed code (not necessarily the same as for alcohol) could serve as sufficient and proportional code for e-cigarettes, but this option has not been considered.

### **2.13 Counterproductive social cost of reduced quitting and extra harm**

The loss of appeal that will arise from medicines regulation will have an impact on the number of smokers quitting compared to continuing with the *status quo* or applying some basic regulation. This possibility is real and important as it involves human life and the core purpose of the Department of Health. It is acknowledged but not quantified in the MHRA impact assessment:

*47. [...] Licensing ENDS is likely to erect a barrier to entry into the market, thus limiting the competition and innovation that would otherwise have driven prices downwards. By itself this would represent a reduction in consumer welfare but if additionally it means that fewer smokers switch to ENDS [Electronic Nicotine Delivery System] than otherwise have been the case, then it is possible that the health losses would be significant.*

This understates the problem – it is not just a matter of higher prices but dramatically contracted product range and loss of appeal that reduce switching. The value of the health gains associated with successful quitting from smoking is very substantial – The Department of Health estimates it to be £74,000. So, by way of example, if less appealing, more expensive products meant 100,000 fewer long-term switchers (1% from 10 million smokers), that would represent a social cost of £7.4 billion. More broadly, it seems self-defeating for the Department of Health to promote a policy for which, “it is possible that the health losses would be significant”. In our view the structural changes described above make this ‘likely’ rather than ‘possible’, but it clearly should be explored in greater depth.

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<sup>24</sup> Advertising Standards Authority, Alcohol Advertising <http://www.asa.org.uk/News-resources/Hot-Topics/Alcohol.aspx> – accessed 15 September 2013.

## **2.14 Unintended consequences – home production, internet sales and black market**

Applying medicines regulation would change what can be sold legally in the UK or EU, but it may not change what users want to use. In its promotion of a highly burdensome and restrictive regime, the government has not considered how users will respond. It is possible that it will induce higher health and safety risks by creating an incentive for users or informal suppliers to make and mix their own liquids or tobacco extracts. It is likely to lead to import of devices or/and liquids that are not approved, either from illicit sources or from legal producers in third countries. Where e-cigarettes have been banned, for example in Australia and New Zealand there is a flourishing internet trade that allows smokers to use e-cigarettes to benefit their health. These counter-measures by frustrated users are an inevitable consequence of regulating products as medicines when users do accept they are in treatment.

## **2.15 Negative implications outside the UK**

**Retail.** The UK has a 'general sales' categorisation that would allow e-cigarettes to be sold in any retail outlet. However, in many Member States, including Germany and France, sales of medicines are restricted to pharmacies or other approved stores. This may not be a problem within the UK but it is a significant weakness in the proposed Tobacco Products Directive. E-cigarettes would be less available at the times and places that cigarettes are available.

**Appropriate regulation.** The UK contributes to the establishment of international norms, and government should be mindful of its broader interests in free trade and proportionate regulation when it regulates domestically or through the European Union. It is possible for example that the legal weaknesses discussed in section 2.11 could result in a challenge under the WTO Technical Barriers to Trade agreement, for example by Chinese manufacturers excluded from the UK market by excessive regulation.



### 3 Poor regulatory practice

The experience of the e-cigarette industry does not align well with the government's stated approach to regulation. The government's approach is clear:

*"We need to tackle regulation with vigour to free businesses to compete and create jobs, and give people greater freedom and personal responsibility ....I want us to be the first Government in modern history to leave office having reduced the overall burden of regulation, rather than increasing it."* Prime Minister, David Cameron, 6 April 2011.

Despite the considerable harm-reduction and health benefits that will arise from a successful shift from cigarettes to e-cigarettes, the regulatory approach to this industry has been crude and excessive. This section examines some of the problems.

#### 3.1 Inadequate impact assessment

The June 2013 impact assessment prepared to support the government's position in supporting the mandatory application of medicines regulation to e-cigarettes does not adequately assess the major impacts, as discussed above. In particular, it is deficient in its assessment of:

- A proper problem definition and a credible 'market failure' rationale for government intervention – the government is assuming regulators should address issues that are more properly resolved in markets
- Alternative regulatory options that address the objective of meeting the policy objective in the least burdensome manner possible – for example in its 2010 consultation, the Commission suggested it might develop "*specific safety and quality requirements*" – a far more reasonable and realistic approach.
- A case that medicinal regulation is the appropriate and proportionate response to the problem, rather than the most convenient framework to hand
- The impact of imposing a pharmaceutical Good Manufacturing Practice standard on the supply chain used in the current industry – a very significant cost and barrier to entry
- The impact on UK companies that use suppliers outside the EU, usually China-based, that may be unable or unwilling to achieve GMP
- The impact on companies that market many product variations and flavours – reflecting obligation to address the impacts on the industry as it is, not as it would become following regulation
- The impact on SMEs – a requirement of the Regulator's Code
- The negative impacts on health objectives arising from barriers to entry, industry consolidation, and reduction in appeal arising from applying medicines regulation to the e-cigarette category
- The potential for black market development or other unintended consequences
- The e-cigarette industry's self-regulatory code ISE (described by Trading Standards as 'a code any industry would be proud to have' and which forms the basis for a workable regulatory framework.

These issues are fundamental rather than incidental.

### 3.2 Inadequate consultation

There has been negligible relevant consultation on the imposition of medicines regulation.

**European Commission consultation.** It is a requirement of the Treaty on European Union that the Commission should consult on legislative proposals<sup>25</sup>. In 2010, the European Commission consulted on whether e-cigarettes should be brought within the scope of the revision of the Tobacco Products Directive<sup>26</sup>, but not on the proposal to regulate these products as medicines. The consultation document proposed two options. Option 1 offered no change (ie continue with national legislation). Option 2 is as below:

*Option 2 - Extend of the scope of the Directive*

*An extension of the scope of the Directive could be envisaged to include novel forms of oral tobacco, herbal cigarettes, and electronic nicotine delivery systems, insofar as they are not already covered by other EU legislation (food, pharmaceutical). Specific safety and quality requirements would be developed for ENDS.*

This does not even mention the prospect of including medical regulation in the directive (in fact it suggests it would not be needed if they were already covered). Instead it refers to a standard-setting approach. Standard-setting would more proportionate and useful, and would be done under a different regulatory framework that does not involve medicines. Although the proposal for a revised directive was not introduced until December 2013, two years after the closing date to this consultation, the Commission did not find time to consult on the proposal that has actually been made.

**MHRA consultation.** The UK medicines regulator also undertook a consultation in 2010<sup>27</sup>. However, this largely concerned how it should assert its presumed jurisdiction. It proposed three options for nicotine containing products (NCPs):

**Option 1** – *Whether all NCPs should be classified as medicinal products and all unlicensed NCPs be removed from the market within 21 days.*

**Option 2** – *Whether all NCPs should be classified as medicinal products and notice be issued to manufacturers that all marketing must cease by a certain date e.g June 2011. After this date enforcement action would be taken against manufacturers of unlicensed products still on the market.*

**Option 3** – *Do nothing*

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<sup>25</sup> Treaty on European Union, Article 11.1 to 11.3 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:083:0047:0200:EN:PDF>

See for example: 11.3 “The European Commission shall carry out broad consultations with parties concerned in order to ensure that the Union’s actions are coherent and transparent”

<sup>26</sup> European Commission, Public consultation on the possible revision of the Tobacco Products Directive 2001/37/EC, September 2010 [http://ec.europa.eu/health/tobacco/consultations/tobacco\\_cons\\_01\\_en.htm](http://ec.europa.eu/health/tobacco/consultations/tobacco_cons_01_en.htm)

<sup>27</sup> MHRA, Public consultation (MLX 364): The regulation of nicotine containing products (NCPs). February 2010 <http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON065617>

*The Government supports Option 1, which is in line with current practice. Views are being sought on these options.*

It should be clear from the framing of these options and the government's preferred option that this was a consultation on imposing a ban not on finding a workable way to develop this industry under a medical licensing regime. Indeed the consultation contains no information and seeks no views on what medicines regulation would mean to this industry. The MHRA was strongly criticised for this consultation by the Regulatory Policy Committee<sup>28</sup>.

*The RPC is of the opinion that the IA and consultation letter do not provide sufficient evidence to suggest that there is a significant risk to public health from currently unlicensed NCPs which would justify the future regulation of these products. MHRA should have made clearer what evidence is available to suggest there are safety and public health concerns about these products and considered a wider range of policy options before consulting on the introduction of a mandatory licensing requirement for all NCPs. In addition, the data and assumptions used in the IA for estimating the costs and benefits of the new regulations do not appear to be robust.*

Despite these serious failings, there has been no further consultation since 2010. Policy has proceeded through a series of announcements of settled decisions

### **3.3 Narrow sources of advice – Commission on Human Medicines**

On 12 June 2013, the MHRA and Department of Health announced that e-cigarettes would be regulated as medicines in the UK<sup>29</sup>. It released a number of papers<sup>30</sup>, including the previously confidential advice and proceedings of the Commission on Human Medicines that had advised on this course<sup>31</sup>, albeit partially redacted. The e-cigarette industry has not had the opportunity to comment on these papers before the settled decision was announced. However, they were open to a campaigning group, Action on Smoking and Health, which had a member on the relevant ad hoc working group of the Commission on Human Medicines. The working group does not have a diverse membership and, so far as we can tell, no experience of business or consumer goods. Concerns have been raised about extensive conflicts of interest<sup>32</sup>.

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<sup>28</sup> Regulatory Policy Committee, Consultation on regulation of nicotine containing products: opinion 2010  
<http://regulatorypolicycommittee.independent.gov.uk/wp-content/uploads/2010/06/MHRA-Nicotine-Containing-Products-final-opinion-for-publication.pdf>

<sup>29</sup> Technically, this was an announcement of the UK's support for the application of medicines regulation through the EU Tobacco Products Directive, and would therefore be subject to the passage of the proposed directive through the EU legislature.

<sup>30</sup> See papers on MHRA's *Nicotine containing products* web page.  
<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice%E2%80%93M%E2%80%93T/Nicotinecontainingproducts/index.htm>

<sup>31</sup> Committee on Human Medicines, CHM Working Group on Nicotine Containing Products (minutes 17 January 2013)  
<http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con286838.pdf>

<sup>32</sup> The Times, *Advisers on e-cigarettes 'failed to declare their interests' in Big Pharma's products*, 26 August 2013  
<http://www.thetimes.co.uk/tto/business/industries/consumer/article3852342.ece>

### 3.4 Persisting with an out-dated policy

We believe the decision to apply medicines regulation to e-cigarettes is largely an artefact of history that has not been adequately challenged in the light of changing circumstances.

**Flawed policy origins.** The policy of applying medicines regulation to all non-tobacco nicotine containing products was first formalised by the last government in its 2010 policy statement, *A smoke free future*<sup>33</sup>. The support for 'harm reduction' was evident in broader indications approved for NRT in 2005 and 2006, and the granting of a harm reduction indication for an NRT inhaler in 2009<sup>34</sup>. These products were already licensed as medicines for smoking cessation. In February 2010, the MHRA also published its consultation on nicotine containing products. The government clearly regarded e-cigarettes ('unlicensed nicotine containing products') as a problem and its stated policy was to have them all removed from the market within 21 days by classifying them as medicines<sup>35</sup>. The basis of the policy therefore is the extension of NRT to harm reduction uses combined with the use of medicines regulation to ban other nicotine products. This is a fundamental weakness: the key to harm reduction is not an extended use of a smoking cessation medicine, but identifying and encouraging relatively safe but effective and pleasurable alternatives to smoking.

**Failing to learn from experience.** At that time, e-cigarettes were much less well known and not as widely used. However, this policy suffered a set-back when hundreds of satisfied e-cigarette users responded to the consultation with accounts of how their health had been transformed with the aid of unlicensed products. The newly elected government inherited the policy and was forced to back down from the intention to remove all unlicensed products in 21 days. A further 18-month period of research was announced. However, in the course of that there was no further consultation or public examination of other options. It was mainly left to the MHRA and its Commission on Human Medicines to do the further work. Unsurprisingly, they viewed this as a problem for medicine regulation. The reliance on the MHRA and its advisory bodies is a significant source of distortion in the options appraisal process – they only have the purpose of regulating medicines. It should be for the *Department of Health* and its ministers to re-evaluate regulatory options in the light of new experience – including the rapid growth, popular appeal of e-cigarettes and much more published literature on their safety and effectiveness. Whilst it is clear that the MHRA is making some efforts to tailor its approach to medicines regulation to address the realities of this non-medical industry, it is highly constrained: both by the medicines regulatory framework *and* by the need to treat other for nicotine products Marketing Authorisation holders and applicants to the same exacting standards.

### 3.5 Poor regulator practice and accountability

Successive governments have been alive to the dangers to business and the economy of overzealous

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<sup>33</sup> HM Government, *A smoke free future: a comprehensive tobacco control strategy for England*, February 2010. [http://webarchive.nationalarchives.gov.uk/20100509080731/http://dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalasset\\_s/@dh/@en/@ps/documents/digitalasset/dh\\_111789.pdf](http://webarchive.nationalarchives.gov.uk/20100509080731/http://dh.gov.uk/prod_consum_dh/groups/dh_digitalasset_s/@dh/@en/@ps/documents/digitalasset/dh_111789.pdf)

<sup>34</sup> See minutes of the Commission on Human Medicines, October 2009. [www.mhra.gov.uk/home/groups/pl-p/documents/websiteresources/con068574.pdf](http://www.mhra.gov.uk/home/groups/pl-p/documents/websiteresources/con068574.pdf)

<sup>35</sup> MHRA, Public consultation (MLX 364): The regulation of nicotine containing products (NCPs). February 2010 <http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON065617>

or inappropriate regulation. Since the Hampton review of 2005 and Legislative and Regulatory Reform Act 2006, there has been statutory guidance and codes covering the way regulators should undertake their duties with respect to business. Following announcements by the Chancellor in the 2012 Autumn Statement, the Department of Business Innovation and Skills (BIS) released new guidance designed to improve the interaction between non-economic regulators and business. There is a new statutory Regulators' Code<sup>36</sup> (which supersedes 2007 Regulators' Compliance Code<sup>37</sup>) and new guidance on Accountability for Regulator Impact<sup>38</sup>.

All of this guidance stresses the importance of proportionality and minimising burdens to the extent possible. The problems with regulation of the e-cigarette industry are in part due the Department of Health and in part to the MHRA. It is the Department that is responsible for determining the overall policy. The MHRA only has powers to act as a medicines regulator and can only hold discussions about application of the Medicines Act. It is the Department that should be open to a discussion of alternatives. In its 2010 consultation, MHRA did not consider any options other than medicines regulation for e-cigarettes (other than 'do nothing', which it dismissed). But the guidance suggests a much broader assessment should have been made:

*3.1 Regulators should consider the impact that their regulatory interventions may have on economic progress, including through consideration of the costs, effectiveness and perceptions of fairness of regulation. They should only adopt a particular approach if the benefits justify the costs and it entails the minimum burden compatible with achieving their objectives. (Regulators' Compliance Code)*

The guidance stresses that special attention should be paid to the impact on small business and the actual business they are engaged in:

*3.3 Regulators should consider the impact that their regulatory interventions may have on small regulated entities, using reasonable endeavours to ensure that the burdens of their interventions fall fairly and proportionately on such entities, by giving consideration to the size of the regulated entities and the nature of their activities. (Regulators' Compliance Code)*

Despite this, the MHRA's 2013 IA is framed around a large company business model with a uniform high volume product. It pays no attention to the e-cigarette SMEs with diverse product range.

The guidance stresses regulators should provide simple and straightforward ways to engage with those they regulate and hear their views. Indeed the Accountability for Regulatory Impact guidance includes a good practice example from the MHRA:

***Good Practice Example:***

*The Medicines and Healthcare Products Regulatory Agency (MHRA) regularly co-produce*

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<sup>36</sup> Department for Business, Innovation and Skills, Better Regulation Delivery Office. Regulators' Code. July 2013  
<http://www.bis.gov.uk/assets/brdo/docs/publications-2013/13-1016-regulators-code.pdf>

<sup>37</sup> BERR, Regulators' Compliance Code: statutory code of practice. December 2007  
<http://www.berr.gov.uk/files/file45019.pdf>

<sup>38</sup> Department for Business, Innovation and Skills, Accountability for Regulator Impact: Guidance  
[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/224155/bis-13-1040-accountability-for-regulator-impact-guidance.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/224155/bis-13-1040-accountability-for-regulator-impact-guidance.pdf)

*assessments of the impact of their regulatory changes with their Trade Associations. They believe that this encourages greater clarity about the impact of new proposals and increases the likelihood of agreement regarding the costs of the change.*

While the MHRA may operate in this consensual manner with the pharmaceutical industry, it has not co-produced an impact assessment or achieved agreement on likely costs and impacts with e-cigarette companies or their trade associations. It has held meetings with industry representatives, but these have been more about explaining its plans than listening to the industry or understanding their products, their consumers' needs, how the industry operates its concerns.

### **3.6 Overlooking e-cigarette industry efforts to manage risk**

An important principle established in the new Regulators' Code is:

*3.4 Regulators, in making their assessment of risk, should recognise the compliance record of those they regulate, including using earned recognition approaches and should consider all available and relevant data on compliance, including evidence of relevant external verification.*

There is in fact an e-cigarette industry code, the Industry Standard of Excellence, developed and managed by the Electronic Cigarette Industry Trade Association, ECITA<sup>39</sup>. This is a process of advising and auditing compliance with the body of existing regulation that applies to e-cigarettes. One option would be to develop and formalise this standard, strengthen governance and auditing, and to use this as way of assisting Trading Standards Officers in applying standard health, safety and consumer protection law.

### **3.7 E-cigarettes as a 'challenger business' held back by ill-fitting regulation**

**Red Tape Challenge.** The government introduced the Red Tape Challenge to tackle unnecessary or excessive regulation. It introduced a theme aimed at disruptive business models or 'challenger businesses'<sup>40</sup>. E-cigarettes are clearly a 'challenger' industry, and for the investment bank Goldman Sachs, e-cigarettes are first in its list of eight globally disruptive technologies<sup>41</sup>. E-cigarettes could rapidly disrupt the entrenched and harmful cigarette-based business model of the tobacco industry, with some investment analysts seeing e-cigarettes overtaking cigarettes in 10 years. If that happened it would be one of the most dramatic public health innovations of all time. However, the proposal to regulate these products as medicines, very closely fits the Red Tape Challenge problem definition for disruptive business models:

*"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".*

This is clearly the case with medicines regulation and e-cigarettes, and we believe the Minister

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<sup>39</sup> ECITA, Industry Standard of Excellence, web page <http://www.ecita.org.uk/theise.html>

<sup>40</sup> Cabinet Office, Red Tape Challenge: disruptive business models / challenger businesses. <http://www.redtapechallenge.cabinetoffice.gov.uk/disruptive-business-models/>

<sup>41</sup> Tyler Durden (Zero Hedge blog) *Goldman's Top Disruptive Themes*, August 2013 <http://www.zerohedge.com/news/2013-08-08/goldmans-top-disruptive-themes>

should welcome a Red Tape Challenge to this policy.

**Regulatory Policy Committee.** As noted above, the RPC has already scrutinised the 2010 MHRA consultation. However, it is unclear what came of its involvement or whether it has returned to this issue now there is a new Impact Assessment. The RPC has been given particular responsibility for disruptive industries<sup>42</sup>:

*Ministers have also asked the RPC to play a stronger role in relation to regulatory barriers preventing new innovative businesses entering markets or where incumbent “challenger businesses” are being unjustifiably hampered by rules, regulations and behaviours.*

We would welcome the greater involvement of this committee and its independent and robust approach to good regulation, especially with its interest in challenger businesses. It would also provide a useful counterweight to the medically dominated Commission on Human Medicines.

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<sup>42</sup> Regulatory Policy Committee home page [\[link\]](#) – accessed 14 September 2013.

## 4 What should happen now?

The government should revisit the policy of treating e-cigarettes as medicines for the reasons given in this note.

The government should:

- Immediately reserve its position on e-cigarettes (Article 18) in the context of the Council deliberations on the Tobacco Products Directive. The French government did exactly this at the Health Council meeting of 21 June 2013. The UK government should do the same until it has properly assessed the impacts and ministers are clearly sighted on the consequences for the businesses and users involved and the potential damage to public health.
- Initiate a 'Red Tape Challenge' process on the application of medicines regulation to e-cigarettes under the 'challenger business' theme of the Red Tape Challenge. This should consider alternative approaches, for example standard setting.
- Prepare an updated Impact Assessment that addresses the deficiencies raised in this report and properly assesses the impacts on the existing e-cigarette industry.
- Invite the Regulatory Policy Committee to examine the current proposals, the impact assessment and process followed and to provide advice to ministers.

The Department of Health, with support from the Department for Business, Innovation and Skills should:

- Urgently examine non-medicines options for proportionate regulation that meets the government's better regulation and red tape objectives. The MHRA is bound to medicines regulation and cannot therefore do this.

The E-cigarette industry should:

- Commit to strengthening and formalising its own code, the Industry Standard of Excellence, and to do more to assist trading standards officers in applying risk-based regulation.



# Annex: Directives and regulations applicable to e-cigarettes

## General safety

General Product Safety Directive [2001/95/EC](#)

[http://europa.eu/legislation\\_summaries/consumers/consumer\\_information/l21253\\_en.htm](http://europa.eu/legislation_summaries/consumers/consumer_information/l21253_en.htm)

The [RAPEX system](#) – notification and alerts of dangerous products

[http://ec.europa.eu/consumers/safety/rapex/index\\_en.htm](http://ec.europa.eu/consumers/safety/rapex/index_en.htm)

[Technical Standardisation](#) under Regulation [1025/2012](#) and related legislation (an option not so far used, but could be used to set performance or design standards)

[http://ec.europa.eu/enterprise/policies/european-standards/standardisation-policy/general-framework/index\\_en.htm](http://ec.europa.eu/enterprise/policies/european-standards/standardisation-policy/general-framework/index_en.htm) and [http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:316:0012:0033:EN:PDF)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:316:0012:0033:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:316:0012:0033:EN:PDF)

## Packaging and labelling

Dangerous Substances Directive [67/548/EEC](#)

[http://europa.eu/legislation\\_summaries/consumers/product\\_labelling\\_and\\_packaging/l21276\\_en.htm](http://europa.eu/legislation_summaries/consumers/product_labelling_and_packaging/l21276_en.htm)

Dangerous Preparations Directive [99/45/EC](#)

[http://europa.eu/legislation\\_summaries/consumers/product\\_labelling\\_and\\_packaging/l21273\\_en.htm](http://europa.eu/legislation_summaries/consumers/product_labelling_and_packaging/l21273_en.htm)

Classification, Labelling and Packaging of Substances and Mixtures – the CLP [Regulation 1272/2008](#) applies from 2015.

[http://europa.eu/legislation\\_summaries/consumers/product\\_labelling\\_and\\_packaging/ev0013\\_en.htm](http://europa.eu/legislation_summaries/consumers/product_labelling_and_packaging/ev0013_en.htm)

## Chemical safety

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) [Regulation \(EC\) 1907/2006](#)

## Electrical safety

Low Voltage Directive [2006/95/EC](#) [http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006L0095:en:NOT)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006L0095:en:NOT](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006L0095:en:NOT)

Electro-Magnetic Compatibility Directive [2004/108/EC](#) [http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0108:en:NOT)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0108:en:NOT](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0108:en:NOT)

Restriction of Hazardous Substances (RoHS) Directive [2011/65/EU](#) (where appropriate) <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:en:NOT>

Waste Electrical and Electronic Equipment (WEEE) Directive [2012/19/EU](#)  
[http://ec.europa.eu/environment/waste/weee/index\\_en.htm](http://ec.europa.eu/environment/waste/weee/index_en.htm)

Batteries Directive [2006/66/EC](#) <http://ec.europa.eu/environment/waste/batteries/>

## **Weights and measures**

Making-up by weight or by volume of certain prepackaged products – Directive [76/211/EEC](#)  
[http://europa.eu/legislation\\_summaries/consumers/product\\_labelling\\_and\\_packaging/l32029\\_en.htm](http://europa.eu/legislation_summaries/consumers/product_labelling_and_packaging/l32029_en.htm)

Nominal Quantities for Prepacked Products Directive [2007/45/EC](#) <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007L0045:en:NOT>

## **Commercial practice**

Sale of consumer goods and associated guarantees [99/44/EC](#)  
[http://europa.eu/legislation\\_summaries/consumers/protection\\_of\\_consumers/l32022\\_en.htm](http://europa.eu/legislation_summaries/consumers/protection_of_consumers/l32022_en.htm)

Distance Selling Directive [97/7/EC](#)

Directive on Electronic Commerce [2000/31/EC](#)  
[http://europa.eu/legislation\\_summaries/information\\_society/other\\_policies/l24204\\_en.htm](http://europa.eu/legislation_summaries/information_society/other_policies/l24204_en.htm)

Misleading and Comparative Advertising Directive [2006/114/EC](#)  
[http://europa.eu/legislation\\_summaries/consumers/consumer\\_information/l32010\\_en.htm](http://europa.eu/legislation_summaries/consumers/consumer_information/l32010_en.htm)

Unfair Commercial Practices Directive [2005/29/EC](#)  
[http://europa.eu/legislation\\_summaries/consumers/consumer\\_information/l32011\\_en.htm](http://europa.eu/legislation_summaries/consumers/consumer_information/l32011_en.htm)

## **Data protection**

Protection of Personal Data – Directive [95/46/EC](#)  
[http://europa.eu/legislation\\_summaries/information\\_society/data\\_protection/l14012\\_en.htm](http://europa.eu/legislation_summaries/information_society/data_protection/l14012_en.htm)