Regulation of e-cigarettes – general ideas

written by Clive Bates | 5 May 2014



Be careful out there…

I'm chairing a panel on "Vapor Industry Standards" at the SFATA spring conference today, and thought it was a good day to publish some general thoughts on regulation. This is part one of two… I always learn a lot at gatherings like this, so I will publish more specific thoughts on nicotine regulation after the conference once I have ~~stolen~~ digested all the good ideas and insights. I hope this prompts discussion and is a useful step on the road to the must-attend Global Forum on Nicotine in Poland at the end of June, where further discussion will follow.

Introduction

All responsible players in the e-cigarette industry want some sort of regulation or standard setting for e-cigarettes – but what should those standards be? The industry recognises that dangerous products, disreputable marketing practices, poor user experience can harm the whole category even if caused by a single firm or product, and consumers tend to agree – up to a point. On the other hand, too much or the wrong sort of regulation, and there can be adverse effects for businesses, consumers and public health. In a situation, where the new products

are competing with a dangerous established incumbent, cigarettes, too much regulation of the wrong type can amount to a regulatory protection of the product that all agree to be the most harmful. It is imperative to avoid that error, but how do we strike the right balance?

Defining the problem

The first question should be "what is the problem the proposed regulation is intended to address?". After ASH published data on e-cigarette use in Britain, showing an extremely encouraging picture from a public health perspective, I am tempted to ask "what exactly is the problem?" and why does anything need to be done *at all* beyond the normal consumer protections? I do think some specific regulation is justified as it happens, and I will discuss that below.

Is there a common language for discussion the regulatory challenges?

Many public health advocates adopt the language of pharmaceutical regulation when discussing e-cigarettes, stressing 'safety, quality and efficacy' of e-cigarettes. However, this is grounded in a long-standing and remarkably persistent misunderstanding of the role these products play. E-cigarettes are legal recreational drugs, not 'smoking cessation' medicines. These words can be misleading because they have meanings related to specific medical challenges, which do not easily translate to recreational drug use:

- **Safety:** primarily refers to the active drug and to side effects or drug interactions. We already know nicotine is safe enough to be on widespread sale in NRT or tobacco. Obviously, there is a safety agenda for e-cigarettes related to mechanical, thermal, electrical safety and contaminants in ingredients and breakdown products in vapour. But this is different to the meaning in medicines regulation.
- **Quality:** in the pharma mindset this is really about achieving consistency and stability of dose delivery – important for drugs, less so for recreational nicotine products. Obviously, there is a quality agenda for e-cigarettes just as there is for any other products, but it is more usual for consumers to 'regulate' that through what they decide to buy and keep buying.

- **Efficacy:** this really refers to whether a medicine does what it says – whether it is effective in treating or preventing disease or beneficially altering physiological functions. E-cigarette manufacturers generally do not make therapeutic claims to 'treat or prevent disease', and the question of whether they are an adequate substitutes for smoking is highly individual and product specific, involving a wide range of factors, not just nicotine pharmacokinetics.

Where should a regulator be involved, and what is a matter for market forces?

It is important not to rely on regulators to achieve things that should emerge from the interactions of consumers and producers in a market. As is the case with food, it is fine to ask a regulator to ensure that cheese is not full of Listeria, but it is not the job of a regulator to determine what a good cheese is. Regulators are there to guard consumers from risks to their health and safety and to ensure they are not misled.

Similarly, the role of the law in regulating use of vapour products in indoor public spaces is excessive. The coercive powers of the law should be reserved for situations where there is material harm to bystanders or workers – or perhaps a collective action problem that does not deliver adequate smoke-free places. The decisions on vaping should really be left to the owners or operators of public spaces, and controlled by standard occupational air quality limits as a protective floor standard.

Is the problem already covered by other regulation?

There has been a (misplaced) panic in some quarters about children drinking toxic e-liquid. There is already extensive regulation in the European Union (the CLP regulation) covering classification, labelling and packaging of hazardous substances. Not only is this built on decades of experience and design evolution, it is based on an established approach to managing these risks. It provides everything needed to address the risks arising from containment of e-liquids. More internationally, there are established standards, ISO 8317 for reclosable packaging. It's not hard, the industry should just comply with these and thus deal

with the issue.

Understanding the costs of regulation

Regulation is not a one way bet: more regulation does not necessarily mean a better safer world. It is for this reason that many governments have developed machinery for challenging 'red tape' and for improving the quality of regulation. Negative effects of regulation include:

- Increased costs in design, manufacturing, distribution and marketing
- Loss of competitiveness to products or jurisdictions more lightly regulated
- Greater complexity requiring specialist staff and more staff time
- Restrictions that limit the potential appeal of the product to the target customer base
- Inhibition of innovation, creativity and experimentation
- Slowing the pace of innovation
- Diversion of staff time and executive attention to compliance activity at the expense of customer focus – it may even negatively contaminate the creative culture of a company
- Reducing the diversity of products available and eliminating niche products for which the costs of regulation and compliance exceed the market value
- Increased concentration of firms and elimination of small players – relatively light regulation (e.g. food) allows large players to coexist with a long tail of small players. Heavy regulation does the opposite.
- Vulnerability to interest-group lobbying or firms seeking commercial advantage through regulations that favour them

It is for these reasons that governments have established principles that aim to constrain regulators to be evidence based, proportionate, non-discriminatory – see below. They are also reasons why proper impact assessment is essential and that benefits of regulation can be shown to justify the costs.

Principles of good regulatory policy and practice

Much has been written on principles of good regulation. The new 'Regulators' Code' in the UK is a good example of the type of principles applied. I'm not going to draw all the various sources (EU, UK, US etc) together but I would suggest the

following principles are relevant and commonly found in the 'good regulation' literature. In each jurisdictions there will be different emphasis and legal standing, but the ideas will be basically the same…

Evidence-based: in departing from general commercial freedoms, some evidence or good reasons are required that intervention is necessary and justified to control risks or realise opportunities. The evidence should show that the proposed regulation addresses the problem that justifies it.

Risk based: regulation should identify and manage material risks to health, safety, the environment and to the consumer. A risk assessment framework would also recognise risks or unintended consequences that might arise from regulation itself – for example in the case of e-cigarettes, a reduction in consumer choice, a loss of innovation, which may in turn lead to more smoking. Risk-based also means recognising that society has a 'risk appetite' and a level of 'tolerability of risk' that is above zero – we do not try to eliminate all risk. It is not the role of regulators to manage risks down to the minimum possible level, but to find an acceptable level of risk without creating excessive or 'disproportionate' costs and to use an appropriate risk management framework.

Proportionate: that setting regulatory standards should produce material benefits, or risk reductions, that people value and that the costs and burdens of regulation are not excessive compared to the benefits. This important principle pervades regulatory good practice, but is often overlooked.

Non-discriminatory: comparable situations must not be treated differently and different situations must not be treated in the same way unless such treatment is objectively justified. This means consistent approaches to risk should be taken across different products, processes and techniques – and that products that pose low or negligible risk should not be treated in the same way as products that pose high risks. Regulation should not be a form of trade protectionism or an anti-competitive regime designed to provide unjustified advantages to particular businesses.

Lawful: regulations designed to achieve a given outcome should not violate established legal principles. In the case of the EU, this means regulation should have a robust legal base and not infringe general principles of the EU

treaties (including those above). For the US, regulations should not violate the constitution. It may also mean complying with other international treaties or conventions such as the Technical Barriers to Trade treaty of the WTO or respecting legal principles in relation to patents or intellectual property. It might be that a regulator regards these principles as wrong or obsolete, but that is a cause for amending them if they can gain agreement, not for overriding or ignoring them.

Legitimate: regulators are granted powers by a legislature (parliament), but should not misuse those powers to do things that go beyond the intent of the legislature. For example, a regulator could demand evidence that it is impossible for a producer to provide (e.g. asking questions that would require a 60 year cohort study to resolve). In doing so they would create a a *de facto* ban on the products, even though that was never the intention of the legislature.

Engaged: regulators should consult those they intend to regulate and those who they hope to be the beneficiaries of regulation. Regulators should work with industry representatives and individual firms to understand costs, benefits and burdens of regulation and ensure these are proportionate to the benefits and kept to a minimum consistent with achieving the public policy objectives.

Transparent: regulators should ensure that clear information, guidance and advice should be available to help those they regulate meet their responsibilities to comply. In the case of the new FDA deeming regulation for example, it is impossible for e-cigarette producers to know what hurdles they will be required to surmount to have their products approved as 'new tobacco products'.

Accountable: regulation should be based on clear evidence based documented justification and impact assessment, that examines all the costs and benefits that would arise from regulation. Regulators should expect scrutiny and challenge within their own government and should be ultimately open to challenge in court if their actions are disproportionate or unjustified.

Stable: regulation should not be arbitrary or capricious but should set a clear medium term direction that can be built into product design, supply chains

and marketing practice. Over time, regulation should evolve in predictable ways with plenty of time for adjustment.

Efficient: regulators do not have unlimited resources and should not design schemes they are incapable of implementing. They should focus their efforts on the greatest risks and the commercial entities most prone to non-compliance. Where a mature industry can show effective self regulation, regulators should be testing the integrity of the system rather than duplicating it. Regulators should be sparing in requesting information – asking for data only if it has a place in making a regulatory decision or is necessary for consumer information. They should always be asked: why do you need this and what will you do with it? Regulators should not be a significant barrier to legitimate commerce, and should be rapid in making determinations, ideally with a service level agreement.

Businesses and consumers involved should be assertive about these principles and not deferential to regulators. Regulators are there to serve the public and to create good conditions in the economy, not just to wield arbitrary powers – the principles above are designed to do that.

The Precautionary Principle – misunderstood and abused

I increasingly think that the precautionary principle, a worthwhile idea, has become the last refuge for scoundrels with a regulatory mission but no evidence to support it. The European Commission published useful guidance on the precautionary principle in 2000. It sets out six guidelines:

> *Where action is deemed necessary, measures based on the precautionary principle should be, inter alia:*
> *• proportional to the chosen level of protection,*
> *• non-discriminatory in their application,*
> *• consistent with similar measures already taken,*
> *• based on an examination of the potential benefits and costs of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis),*
> *• subject to review, in the light of new scientific data, and*
> *• capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.*

For our purposes the key guideline is the 4th in the list above: the requirement to apply a symmetric assessment of risks and benefits arising from both regulatory intervention and non-intervention. In other words, if a regulator wants to come down heavily on a product like e-cigarettes because of hypothetical dangers, it has to take into account the lost benefits that might arise if it bans, restricts or otherwise reduces the positive potential of the product. For e-cigs this is particularly salient as the benefits are to health, not just economic. This symmetry is almost always overlooked when activists make arguments using the precautionary principle.

Precautionary principle and snus. Disgracefully, 'health' campaigners and the European Commission continue to apply the precautionary principle opportunistically (and unscientifically) to justify banning snus. Faced with insurmountable evidence that the marketing of snus has been highly beneficial in Sweden and Norway, they clutched at the PP to argue that something might still go wrong. In its impact assessment for the directive the European Commission argued:

> *Lifting the ban on oral tobacco (option 1) would have adverse health effects. It could also attract new tobacco users who would otherwise not have taken up tobacco consumption. Moreover, it would have a negative health impact on smokers who would otherwise have quit smoking, but who continue to use both FMC/RYO and STP (dual use) and for smokers taking up STP use who would otherwise have quit using tobacco altogether. For individuals replacing FMC/RYO with STP completely, the health effects would be positive. Considering the uncertainty in relation to substitution, an overall negative outcome under option 1 cannot be excluded. Therefore, this option raises doubts in terms of coherence with the precautionary principle*

This reasoning is full of errors and fails just about every one of the Commission's own precautionary principle guidelines, but especially the one considering about potential benefits of non-intervention. Lars Ramström and I wrote a detailed rebuttal to the Commission's case, dealing with the abuse of the precautionary principle at section 4 on page 16: *A critique of the scientific reasoning supporting the proposed measures relating to oral tobacco* . They didn't reply of course, but I hope one day there will be a legal challenge to this especially harmful directive where we can parade this in front of the court.

Finding the public health optimum

The regulatory objective is not to create the safest cleanest possible products,

with the most risk averse advertising and most restrictive commercial practices. The perfectly safe product that no-one wants to use is of no value in public health terms. For the optimum public health outcome, the benefits to smokers who switch to e-cigarette must be weighed alongside the risks to people who use e-cigarettes. If regulation designed to reduce the risk of e-cigarette also makes them less attractive or reduces the choice offered to smokers the overall impact of 'tougher' regulation may actually increase harm to health.

The key is to retain the appeal to smokers and to balance risks associated with the e-cig products with risks of continuing but avoidable smoking if smokers are deterred from switching. In other words, the opportunity to have smokers switch should play a large part in the regulatory optimisation and therefore sustaining and encouraging the appeal of these products to smokers matters a great deal. 'Appeal' is not something regulators are used to dealing with. Most regulated products are not in competition with a pervasive market leader than is far more dangerous that the new entrant category. Three examples serve to illustrate the point:

1. Flavours. Medicines do not need to come in 300 flavours, they just need to be palatable. But flavours are integral to the e-cigarette value proposition to smokers – frivolity, experimentation and personalisation are part of the appeal. So if a regulator is excessively risk averse towards flavours (for example requiring that they have been tested for medical inhalation use) then they risk causing consequential harm through extra smoking that may be far worse than the harm they wish to avoid by limiting the available choice of flavours.

2. Regulatory costs. Regulation may raise costs of e-cigarettes, but there are several elasticities to consider – if the price goes up, then all other things being equal, the demand will fall in relative terms. This this would likely mean more smoking than there otherwise would be. So any estimate of the health value of raising costs of e-cigs by imposing exacting standards must be offset be the expectation there is a detriment arising from more smoking. Note that this effect may be offset by greater consumer confidence, and a willingness to pay for quality assured products. So we may wish to strike a balance between customer assurance and excessive cost, bearing in mind, the comparator is smoking. Get this balance wrong, and the regulators causes more harm than they prevent.

3. Limiting nicotine liquid strength. This may appear to have the benefit of reducing the risk of accidental poisoning (a claim wholly without basis – see scientists letter to EC), but it would have the negative effect of removing from the market liquids used by about 25% of users. These users may be those making the initial conversion, or those with stronger dependence on nicotine. Banning these liquids might also mean a loss of innovation – more compact products might benefit from higher nicotine concentrations, for example.

I think the risks of e-cigarette use can probably reduced to a low level quite cheaply and easily, and certainly without elaborate pharmaceutical regulation. The critical challenge for public health is to ensure that highly risk-averse, over-zealous regulators do not wantonly destroy the 'value proposition' of e-cigarettes to smokers and thereby increase risk that they are not directly accountable for in the name of reducing risks they are accountable for.

Population effects – challenge the case for taking these into account

Regulators and many activists evoke the concern over 'population effects' to make a case that a very much safer product than cigarettes might actually be somehow more dangerous. These potentially negative population effects include:

- Increased initiation among non-smokers
- Increased relapse among ex-smokers
- Reduced quitting among smokers
- The general idea that e-cigarettes will 'renormalise' smoking and perhaps increase exposure to secondhand smoke

Is this approach legitimate at all? The motorcycle helmet thought experiment. First of all, we should not simply accept that population effects should form part of regulatory determinations without question. The ethics of this are not at all straightforward – it might mean denying someone a life-saving safer alternative to smoking because *someone else* is using the product in a way the manufacturer or regulator does not intend. Imagine the argument played out for motorcycle helmets. Suppose wearing a helmet inclines some bikers to ride faster because they feel safer – as a result of this 'risk compensation' they may do more more harm to themselves and others as a result. Would we ban motorcycle helmets to stop this? I don't think so. Further, helmets might encourage more

people to ride because it looks safer instead of driving much safer cars – more accidents and greater harm could be the result. But would we deliberately make motorcycling more risky for bikers by banning helmets to prevent motorists 'relapsing' to motorbikes? No. People worry that e-cigarettes might be used for taking illicit drugs, but we don't ban spoons or banknotes because they are used in drug taking. Again, we can't regulate for misuse of things intended to do something else.

Role of the state and individual. I think this gets down to where you stand on the respective role of the individual and the state. In my view, the state should not be an all-controlling health optimiser (and not just because it be bound to make terrible mess of it). For me, the responsibility of the state is to ensure that people are well informed and have good choices they can make. It is not to impose or prevent particular choices – unless they cause harm to others. My own view is that regulators should stick to regulating individual risk for e-cigarettes in the situation where the product is used broadly as intended.

Positive population effects. For each of those negatives listed above, there is a mirror image positive population effect.

- Decreased initiation among non-smokers as adolescents take to vaping instead of smoking
- Decreased relapse among ex-smokers as they can vape instead of going back to smoking
- Increased quitting among smokers as e-cigarettes are used to quit smoking and perhaps as a staging post to quitting nicotine use altogether
- E-cigarettes will further marginalise smoking by popularising an alternative

We should note that in the best studied harm reduction example, snus use in Sweden, activists used the negative list of possible population effects above to campaign for the product to be banned elsewhere in Europe. None of these negative effects materialised but the positive effects are clearly demonstrated in the literature and record low smoking statistics. That would suggest that these benefits may have been foregone in other countries at a cost of harm to health. It didn't change the minds of activists though, which suggests to me these arguments were always just campaign tactics in a vaguely understood ideological campaign. When a regulator or activist raises population effects, they should be

asked to work through how they would handle the snus case, and what lessons they have learned from Sweden and the European Union.

Evidence on population effects: an impossible ask? So far there is nothing to support concerns that e-cigarettes may be causing negative population effects, and to the extent that there is evidence it is consistent with e-cigarettes reducing smoking. But how would a company prove this one way or the other, either in general or, harder still, specifically for its own product? The FDA in its authorisation procedure for new tobacco products (PMTA p15) states:

> *The statute provides that the basis for this finding shall be determined: with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account –*
>
> > *(A) The increased or decreased likelihood that existing users of tobacco products will stop using such products; and*
> >
> > *(B) The increased or decreased likelihood that those who do not use tobacco products will start using such products.*

But how could this be determined? There is no parallel world that can be compared with the real world to see what would have happened in the absence of the product. It would be impossible to do as a trial. It would take years until all the possible transitions between smoking, vaping, dual use and abstinence had worked through. It is impossible to do for a single product, as real world behaviour may involve many different transitions and products.

The prohibitive default. Note that the formulation of population effects is open and symmetric ('increased or decreased likelihood'). But what would the regulator do if the evidence was unclear – as it is likely to be? If they refused to authorise the products in the absence of clear evidence showing no negative population effects, they would potentially be causing population harm by forgoing positive population benefits – exactly what happened over snus in Europe.

Maintaining perspective: keeping comparators in mind

Many commentators have automatically assumed that the best reference point for

considering e-cig regulation is NRT, and that regulation should borrow heavily from that. Whilst one can see the logic, I think that may be worth keeping other comparators in mind instead or as well. NRT has not been especially successful, nor have the manufacturers been very innovative. The best health results achieved have been with smokeless tobacco as a substitute for smoking in Sweden – in this case the regulatory control of the product itself was very light, there were no requirements for pharmacokinetic profiling or requirements for consistent 'dosing' etc. The product functions successfully as an alternative to smoking because it comes positioned as a recreational product, not a smoking cessation aid. No-one takes of 'efficacy' when it comes to snus, it just works out that way. Coffee is also a useful reference point – we do not require regulators to assess caffeine dose and we know users partly control this by choosing Americano or Expresso, or how much coffee they place in a filter. With coffee we do not demand intimate knowledge of the chemistry, even though the high temperature roasting process creates may de novo chemicals, including known carcinogens. The analogy is not exact of course, as vapour is drawn into the lungs, rather then the less sensitive digestive tract for coffee. However, regulators should keep in mind comparators that reflect our normal risk appetites and tolerability of risk.

Watch out for regulatory predators

You can't rely on industry players to identify the right type or stringency of regulation for the *health of the market as a whole or for public health.* This because each is interested primarily in its own position in the market and regulations can work to competitive advantage and disadvantage. So…

Large players may favour raising regulatory barriers to entry to small players, exhausting their balance sheets and borrowing before they can comply

- Pharma companies will want regulation that suits the pharma business model
- Bricks and mortar based companies may talk up peril in internet sales
- Small marketing-orientated companies may wish to cut corners
- Incumbents may favour marketing restrictions in order to hold on to market share
- Cig-a-like manufacturers may see the messy but effective threat from 2nd & 3rd generation tanks and mods as something to slow down or stop dead with regulation

- Most companies want less competition and fewer able competitors – market and consumers usually thrive on the opposite

This isn't to be especially cynical, but it is important for regulators (and public health establishment) to recognise vested interests in regulation, *and these are not always in favour of having looser regulation*. It is no accident that the first company that will bring a product to market in the UK that is fully aligned with the strict medical regulation is likely to be British American Tobacco's subsidiary Nicoventures. It's a credit to that company that it has made the necessary investments of tens of millions of pounds in facilities, staff, IT and science – but making that standard mandatory for the whole category might have had many perverse consequences.

The importance of phasing and time

Generally, the tougher the regime the longer it requires for introduction. Unless authorities are taking emergency action – and there is nothing to justify that with e-cigarettes – they should introduce standards in a way that doesn't needlessly destroy viable businesses selling popular products that are compliant with existing law and are *safe enough*. This doesn't mean that over time we can't raise industry standards to a level that would be highly disruptive if they were introduced overnight right now. The problem with going for tough regulation is that the long lead time means there is weak or no regulation in the interim. So the ideal approach is graduated – the first step will be straightforward safeguards that can be introduced easily, or even just rigorous application of law that already exists. For example, in the EU there is already the Classification, Labelling and Packaging Regulation that governs the containment of hazardous substances. Just gaining compliance with this would be a considerable advance (and render much of the Tobacco Products Directive superfluous).