The case for regulating e-cigarettes as medicines

written by Clive Bates | 6 July 2013

What do the supporters of medicines regulation for e-cigs say, and why are they wrong?

It's quite hard to actually find a coherent case for regulating e-cigarettes as medicines. Mostly those making the case show it *can be done*, but do not show it is the best thing to do or compare it to lower cost, lighter touch alternatives – see the MHRA work on nicotine. But the essence of good policy making is *options appraisal*, not simply justifying the only thing you know about. I have already said quite a bit about the problems of medicines regulations: see *10 reasons not to regulate e-cigarettes as medicines* and *medicines regulation: when caution can kill*, and a briefing on the legal aspects: *are e-cigarettes medicines?* But I thought it might be useful to examine the arguments used by those claiming regulation of e-cigarettes is the only way to go one at a time.

We need to ensure safety…

Short response: *already covered in the legislation that keeps thousands of products safe.*

Products on the European market already have to be acceptably safe under the General Product Safety Directive and the related framework of legislation, which also allows for product or sector-specific standards (eg. cigarette lighters). There are other regulations covering electrical safety, containment and labelling of hazardous substances and various aspects of commercial practice. It is also possible to establish specific European Standards (CEN) with a safety objective should these be needed. This broad framework keeps European citizens safe from thousands of potentially dangerous products (eg. things using mains electricity,

hazardous chemicals like bleach or drain cleaner, things with sharp edges or moving parts etc etc). The primary safety purpose of medicines regulation, however, relates to *the safety of the drug itself* – ie. to unwanted side-effects or drug interactions arising from the potent chemicals in medicines (such as Varenicline). There is no concern about the active ingredient nicotine given how widely it is used. EU legislation is required to use the least burdensome regulation possible to meet the policy objective, and this is it. If vendors want the added hallmark of high safety that comes with a marketing authorisation as a medicine, then they should be free to go through that process. For others, there should be a satisfactory 'floor standard' consistent with the general safety obligations.

We need to ensure quality…

Short response: *quality is driven by primarily consumer choice and suppliers competing. Faulty products and/or dangerous products are covered in consumer protection legisaltion.*

Yes, but only up to a point. For most products, the *market* determines the range of products, prices and spectrum of quality – by 'the market' I mean the evolutionary pressures of consumer preferences, supplier innovation, product quality and price – meaning the bad products fall by the way side. Some aspects of quality are a subset of safety and these are covered by the provisions above. It is also possible to set European Standards for quality if needed. If something simply doesn't work as advertised or claimed, then the product is *faulty*, and covered by the Sale of consumer goods directive 99/44/EC.

A list of applicable legislation, already in force, is available at: E-cigarettes are unregulated, right? (wrong). Those favouring medicines regulation have never shown why these directives, applied purposefully and properly enforced, would not provide a good balance of consumer protection and commercial freedom – especially important where the growth of the market is what gives the public health return. Yet under the treaty (Art 5 TEU Protocol 2), and for sound policy reasons, EU regulators must use the least burdensome regulation available. If vendors want the added hallmark of quality that comes with a marketing authorisation as a medicine, then they should be free to do that, but it should not be a requirement unless there is no alternative.

E-cigarettes have the same function as NRT so deal with them the same way…

Short response: *no they don't. NRT treats nicotine withdrawal. E-cigarettes provide an alternative way to take recreational nicotine.*

This argument goes that e-cigs do the same job as NRT – to quit, to cut down or for dealing with when smoking is banned – so should be regulated in the same way. This couldn't be more wrong and is a source of great confusion amongst health campaigners – users of e-cigarettes, however, are universally clear on the difference. NRT predominantly is used as an aid to manage nicotine withdrawal symptoms during an attempt to stop smoking and nicotine use completely, though has been used 'off license' for nicotine maintenance (this has changed only recently). E-cigarettes are not used therapeutically, but as an *alternative* to smoking and a different way to use nicotine. E-cig users are looking to recreate or improve on the pleasures they experience from nicotine use and smoking, but without the negatives – smell, anti-social aspects and cost may be as important as serious distant health risks – and a sense of fun or connoisseurship. We can call this 'harm reduction' from a public health perspective (and be mighty pleased about it in my case) and many users celebrate the health gains they achieve. But the user's purpose is primarily seeking experience of using a benign recreational drug… see *Are e-cigarettes medicines?* for the legal destruction of this supposed equivalence. These are not medicines any more than caffeine, alcohol or tobacco. There are many things that improve health that are not medicines. More excellent analysis on this by Carl V Phillips *Tobacco harm reduction: it's not just about harm reduction* and Chris Snowdon *Taking the pleasure out of e-cigarettes*. Much mischief follows from this misunderstanding.

We need to ensure 'efficacy'…

Short response: *only if a vendor is claiming some 'effect' – otherwise consumers decide if these products work for them – the normal way with almost all products.*

This confusion arises from the misclassification of e-cigs as medicines by flawed analogy with NRT, as discussed above. If the product is simply a recreational product about which no claim has been made, it is not the job of the regulator to come in and invent some sort of enjoyment or satisfaction standard that these

products must attain. That is a matter for consumer preference and the functioning of the internal market – not least because regulators don't know what consumers want from the experience, don't know how their preferences will evolve etc etc. If a health claim is made, then the product should be evaluated as a medicine, but this should not be a requirement where no claim is made.

Even if medicines can only be sold in pharmacies in some countries, smokers can still get them…

Short response: *to have maximum reach e-cigs need to be as widely available as cigarettes and in equivalent settings – not just sterile pharmacies.*

One of the most serious issues about medicines regulation is the restrictions on availability imposed on licensed medicinal products: in many countries these are 'pharmacy-only'. It is typical of the British only to think of themselves – some medications can be sold on general sales in Britain. But the proposal favoured by many British campaigners would cause huge problems elsewhere, where all licensed medicines are 'pharmacy only'. It is important that e-cigs are not only as widely available as cigarettes, but also in the same *type* of settings – bars, *tabacs*, newsagents, supermarkets, filling stations etc. Again the NRT-equivalence fallacy is the problem. E-cigs are not medicines, and do not generally appeal to users as medicines – so it would be disadvantageous to sell them in sterile medicalised settings.

There are lots of health people, including WHO, would would be happy to see these products banned – a tough regulatory regime might bring them onside

Short response: *that's their problem and a reason not to take their advice or fund them – lawmakers are serving citizens not interest groups.*

It is true that the public health community has more than its fair share of professional zealots, prohibitionists and authoritarians – and that these are also overrepresented in the WHO (see this appalling case if you need convincing that the WHO should be ignored and funding withdrawn). However, it is the job of policy-makers to evaluate evidence and do the right thing for citizens, not to be

intimidated or mislead by elements of the public health community. There is no need for the EU to accept counter-productive policy on e-cigarettes handed down by WHO through the FCTC. The EU has a vote, the FCTC looks for consensus. It would be better for the EU to make a compelling case for a market driven approach underpinned by light touch consumer regulation. It would be better to stop funding WHO to provide dangerous misinformation.

It's not that expensive – the licence fee is a few thousand pounds and big companies will soon take over

Short response: *regulatory costs should always be as low as possible, but fixed regulatory costs reduce diversity, innovation and so limit appeal*.

The starting point for deciding any regulatory approach in the internal market is not whether producers can manage costs of excessive regulation or, more usually, to pass them on to consumers, but what is the lowest regulatory cost consistent with meeting the objectives. So arguments that 'big companies can afford it' should be dismissed as answering the wrong question. In fact, the estimated cost of the the licensing process given by the UK MHRA is not trivial: up to £2,280,000 (present value) or £266,000/year annualised – see its Impact Assessment (note £1.0 = €1.16). And this doesn't cover additional costs associated with upgrading the supply chain to pharmaceutical clean-room standards or the lost revenue costs during the lengthy approval process. These costs may be bearable for vendors of high volume commodity e-cigs. But costs and approval processes like this have impacts: (1) on diversity and niche products – ie they work against having a 'long tail' of differentiated products that each appeal to a small number of consumers, because each product needs an authorisation. (2) They also work against an 'experimental' approach to innovation – try lots of products and see what proves popular. This is common with fast-moving consumer goods, but not the model of innovation that applies in the pharmaceutical industry. (3) There's also a 'chilling effect' on innovation from restrictions the regulator would apply and the developers' perception of how those restrictions might apply, given the cost of being wrong: eg. would they try to get approval for pina-colada or tequila flavour?

It is necessary to certify the manufacturing process as 'GMP' to bring these products up to scratch

Short response: *this is needlessly expensive and difficult given most nicotine is delivered in cigarette smoke*.

Medicines regulation requires these products to be made to an onerous and expensive 'Good Manufacturing Practice' standard. Given that 98% of nicotine is consumed through a filth-laden matrix of micro particles of burning tobacco and hot toxic gases, it's hard to justify going to the other extreme – especially as this will disrupt the supply chain currently supporting the market and add great cost. Yes, it is a ingrained habit of the EU to punish entrepreneurs and small businesses with life-sapping demands, but there really is no need in this case. As with other costs, it needs to be justified as proportionate and non-discriminatory. This standard doesn't apply to foods, alcohol etc and cosmetics use a 'lite' standard for GMP using ISO 22716. In international law (WTO-Technical Barriers to Trade), measures must not be more trade restricting than necessary to meet policy objectives – and the preference is always for performance specifications rather than regulating design or manufacturing unless needed – so that would mean setting a purity standard for an e-liquid for example. It's basically overkill to apply this standard – and therefore not compatible with the EU Treaties.

The UK 'light touch' model is the way to do it

Short response: *you can't assume the UK approach is beneficial or that other countries will approach it in the same way. Such powers should only be given to regulators if risks justify it – and they don't*

UK campaigners and the UK regulator the MHRA have been at pains to stress how 'light-touch' or 'right-touch' their approach would be – how open they would be to 'lifestyle' marketing etc. It remains to be seen how this will work out in practice in the UK. It probably won't be fatal, but I suspect they'll manage to impede progress, diversity and innovation, raise costs and introduce a bland tone to the category that will make it less appealing to smokers – moderate harm, a few thousand needless deaths. But that's just the UK. The bigger problem is that campaigners and regulators in other countries are not so progressive – but this is

EU law and the EU will establish a powerful precedent internationally. Medicines regulation hands very considerable *obstructive powers* to a regulator- at the expense of the commercial freedoms that are the crucial ingredient in gaining widespread uptake. Regulators should not have that power, unless the risks (or possible benefits) justify it. In other countries the regulators are much more hostile and the campaigners creating the climate in which they make decisions are also much more hostile – a good example is the the Australian regulator who is egged on by some very hostile campaigners and prone to political interference.

We need medicines regulation to impose a risk management system and market surveillance

Short response: *this comes of incorrectly thinking of these products as medicines. Most risky products, including cigarettes and alcohol, don't have a 'risk management system' run by each vendor*

No we don't. We don't require tobacco, alcohol, caffeine, salt, motorcycle, sporting gun, condom, cycle helmet [insert potentially risky industry here] to conduct this sort of pro-active market surveillance. Whilst concerns about children using the products when they shouldn't what would it mean for the vendor. Questions of 'dual use' (use with continued smoking) or non-smokers taking up the products are interesting, but that's all. They are primarily an academic concern, albeit interesting, and adults have freedom to do these things if they want to, even if health campaigners disapprove. Risk management systems in medicines regulation have the primary function of detecting adverse side effects, interactions with other drugs or 'contra-indications'. Again, normal standards of producer responsibility should apply. If we think that more than that is necessary, the kind of approach used in cosmetics regulation would be better.

VAT is lower if the products are licensed medicines – that's a benefit

Short response: *VAT concessions are redistributive – someone is paying more tax somewhere else*.

These products are consumer products and should not be provided with tax breaks or through public spending (ie. on prescription) other than in exceptional

cases. Smokers existing spend on cigs should be the primary funding source, and lower costs and no excise duties should allow for savings to the individual. The idea that lower VAT compensates for the higher underlying costs of regulation reflects a misunderstanding of the public finances. Taxes are transfers, regulation actually consumes extra resources. Lower VAT revenues just mean taxes come from somewhere else creating a different cost to the consumer/taxpayer. It isn't a real net saving, though it would have distributional consequences. Again, not every country has the same VAT treatment of pharmaceuticals [EU rates] – for example it is 19% in Germany. It's important not to misunderstand what the VAT break means in the UK and not to generalise this to countries where it doesn't apply.

Medicines regulation allows for control of advertising, packaging and other aspects of marketing – to prevent appeal to non-smokers and children

Short response: *the public health gains come from having as many smokers switch as possible, we should favour as much marketing freedom as possible – the risk to children is small*

Medicines regulation would involve pre-authorisation of several aspects of marketing, branding and advertising by the regulator, and they are sure to be risk averse and reduce creativity and 'edge'. Let us be clear, the big health gains come from as many people switching as possible from smoking – and that is a marketing challenge, in marketeers should be as unfettered as possible. The risks arising from aggressive advertising are negligible – but the upside is potentially huge. The public health challenge has two main dimensions: first, ensuring products that are good enough are available and driven to be better by fierce competition, not protected by regulatory barriers to entry. Second, maximum uptake by smokers driven by effective marketing and a regulatory framework that doesn't render the products boring and unappealing. It is not in the public health interest to create sterile safe products, marketed in a worthy but dull way. Even alcohol – with far more harmful unwanted side effects than e-cigs – does not have a pre-authorisation regime. However, it is not unrestrained either – see Advertising Standards Authority Guidance guidance. Why not something like

this?

By the way, the risk to children from e-cigs is *negligible* – teenage experimentation is inevitable and any prolonged uptake is more likely to be an alternative to smoking (a beneficial early diversion from the much more damaging habit) so excessive weight should not be placed on this risk compared to the public health imperative to persuade adult smokers to switch. See: we need to talk about the children: the gateway effect examined.

Medicines regulation allows for better patient information

Short response: *this isn't the case with NRT – dreary leaflets explain risk at length, but say little useful about the implications of switching from cigarettes*

It is certainly true that the warnings proposed for nicotine containing products are unhelpful: "*This product contains nicotine and can damage your health*" it says in the Commission proposal. Useless communication basically, given that the only interesting risk information about these products is the comparison with smoking. So it might be argued that medicines regulation could do a better job. The trouble is the NRT products inspire no confidence in that respect: here is the Patient Information Leaflet for a Nicorette Inhaler.

Finally, remember the differences…

The excellent European Parliament library briefing on e-cigarettes highlighted the difference in a table.

NRT	electronic cigarette
marketed as cessation aid	marketed as replacement for tobacco cigarette
marketed to health professionals and consumers	marketed to consumers
slow nicotine delivery, low risk of addiction	nicotine 'hit', high risk of addiction
controlled dosage of nicotine	consumer controls the dosage
unattractive by design to avoid 'abuse-liability'	considered attractive, and used in social situations
standardised product with long innovation cycles	wide variety of shapes and flavours, rapid innovation cycles
sold in drugstores and pharmacies	sold through various retail channels and over the internet
subject to clinical trials and approval	subject to product safety legislation (except where regulated as tobacco products or medicines)
claims of efficacy for smoking cessation	no health-related claims are made
produced by pharmaceutical companies	produced/marketed mostly by small and medium-sized enterprises